86-577

Supreme Court, U.S.
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No.

IN THE UNITED STATES SUPREME COURT

October Term, 1986

California Pacific Research, Inc.,
a Nevada Corporation,

Petitioner,

vs.

United States Postal Service,

Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE NINTH CIRCUIT COURT OF APPEALS

Jay H. Geller
GELLER & BOZEMAN
2049 Century Park East
Suite 1200
Los Angeles, CA 90067

Attorneys for
Petitioner
California Pacific
Research, Inc.

IN THE UNITED STATES SUPREME COURT

October Term, 1986

California Pacific Research, Inc.,
a Nevada corporation,

Petitioner,

v.

United States Postal Service,

Respondent.

PETITION FOR A WRIT OF CERTIORARI

QUESTION PRESENTED FOR REVIEW

1. Whether there was substantial evidence to support the Respondent Postal Service's decisions that Petitioner falsely represented that its products will stop hair loss in balding men and will cause the regrowth of hair on bald heads and thereby had engaged in a scheme to obtain money or property through the mails my means of materially false representations in violation of 39 U.S.C. 3005.

LIST OF PARTIES

All parties to this proceeding are identified in the caption above.

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OFFICIAL AND UNOFFICIAL REPORTS
OF OPINIONS OF COURTS AND AGENCIES

The United States Court of Appeals issued an unpublished decision on July 10, 1986, California Pacific Research, Inc. v. United States Postal Service, No. 85-1727.

The United States District Court for the District of Nevada issued an unpublished opinion on January 14, 1985, California Pacific Research, Inc. v. United States Postal Service, No. Civil R-83-172 BRT.

The Administrative Law Judge of the Postal Service issued an Initial Decision on April 9, 1982, In the Matter of the Complaint against New Generation, etc., P.S. Docket No. 11/152.

The Judicial Officer of the Postal Service issued a Postal Service decision on May 13, 1983, In the Matter of the

Complaint against New Generation, etc., P.S. Docket No. 11/152.

GROUNDS FOR THIS COURT'S JURISDICTION

a. The decision of the Court of Appeals for the Ninth Circuit was entered on July 10, 1986.

b. There were no requests for rehearing in the Court of Appeals or requests for orders extending the time for filing a Writ of Certiorari.

c. The statutory provision Petitioner believes confers jurisdiction of this Court is 28 U.S.C. 1254(1).

STATUTES INVOLVED

39 U.S.C. 3005(a) provides, in relevant part:

> Upon evidence satisfactory to the Postal Service that any person is engaged in a scheme or device for obtaining money or property through the mail by means of false representations, * * * the Postal Service may issue an order which -

(1) directs the postmaster of the post office at which mail arrives, addressed to such a person or to his representative to return such mail to the sender appropriately marked as in violation of this section ***; and

(2) forbids the payment by a postmaster to the person or his representative of any money order or postal note drawn to the order of either and provides for the return to the remitter of the sum named in the money order or postal note.

5 U.S.C. 706(2)(E) provides, in relevant part:

To the extent necessary for decision and when presented, the reviewing court shall * * * * -

(2) hold unlawful and set aside agency action, findings and conclusions found to be -

(E) unsupported by substantial evidence in a case subject to Sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute...

STATEMENT OF THE CASE

A. INTRODUCTION

This case originates with an Administrative Complaint filed in August, 1981 by the United States Postal Service seeking

an order to be issued against Petitioner pursuant to 39 U.S.C. 3005(a)(1) and (2) to stop Petitioner from receiving mail pertaining to its New Generation products and having the mail returned to the senders. Under the Statute, an order may issue which directs the return to sender of mail, and the non-payment of postal money orders or notes, and refund to remitters, when it appears, "upon evidence satisfactory to the Postal Service that (Petitioner) is engaged in conducting a scheme or device for obtaining money or property through the mails by means of false representations." 39 U.S.C. 3005.

The Administrative Complaint alleged that Petitioner here (Respondent in the Administrative proceeding) represented that its New Generation products "will stop hair loss in balding men" and "will cause the regrowth of hair on bald heads."

A hearing was held on the Complaint before an Administrative Law Judge on October 1 and 2, 1981 in San Francisco, CA. On the basis of the evidence submitted at the hearing and the briefs and arguments of the parties, the Administrative Law Judge issued his Initial Decision on April 9, 1982, finding that Petitioner represented that its products "will cause the regrowth of hair on bald heads" and that this representation was false in fact. The Administrative Law Judge found that the evidence did not support the Postal Service's contention that Petitioner represented its products will stop hair loss in balding men. The Administrative Law Judge concluded that Petitioner was engaged in a scheme to obtain money through the mail by means of false representations and recommended the issuance of the Order requested by the Postal Service.

Both parties appealed the Initial Decision to the Postal Service Judicial Officer. The Judicial Officer affirmed the Initial Decision with respect to the hair growth claim, but reversed the Initial Decision with respect to the hair loss claim and found that Petitioner did represent its products "will stop hair loss in balding men" and that this representation was false by a preponderance of the evidence. The Judicial Officer issued the orders requested by the Postal Service pursuant to 39 U.S.C. 3005. The parties agreed to a stay of those orders pending exhaustion of all appeals.

Petitioner filed a Complaint for Review in the United States District Court for the District of Nevada alleging that the Postal Service decision was not supported by substantial evidence. On January 14, 1985, the District Court granted

Petitioner's Motion for Summary Judgment concluding (App. p. 46) that:

> ... substantial evidence does not support the Judicial Officer's findings that: (1) New Generation represents it will stop excess hair loss in balding men; (2) New Generation represents it will cause regrowth of hair on bald heads; and (3) that these claims are false as a matter of fact.

Accordingly, the Postal Service Order was set aside.

The Postal Service appealed the District Court decision to the Court of Appeals for the Ninth Circuit. In the decision from which this Petition emanates, the Court of Appeals reversed the District Court holding (App., p. 19):

> Because there was substantial evidence to support the Postal Service's decision that appellee falsely represented that its products will stop excessive hair loss and cause regrowth of hair in men with male pattern baldness the Postal Service's administrative decision must be upheld.

B. Representations Made By Petitioner

1. Introduction

At the time of the filing of the Administrative Complaint, Petitioner marketed two hair care products, New Generation hair and scalp cleanser/conditioner and New Generation shampoo. As application to the issue here, the Administrative Complaint alleged that the products "will stop hair loss in balding men" and "will cause the regrowth of hair on bald heads."

The Administrative Complaint alleged that Petitioner's promotion of its products commenced with an advertisement in the Sacramento Bee newspaper on August 14, 1980. The advertisement was addressed to people who had an interest in baldness, and told them that Petitioner may have an unspecified answer for them. Interested persons were encouraged to call

Petitioner for more information or to watch an upcoming television program.

The Complaint further alleged that interested persons, upon contacting Petitioner, would receive certain materials, set forth at pages 4 - 6 of the April 9, 1982 Initial Decision. These materials consisted of reprints of newspaper articles appearing in publications of general circulation not authored by Petitioner, and a product order form. The materials generally discuss the background of Petitioner's president, how the products came to be developed, and user experience with the products. The materials also discuss male pattern baldness, the ingredients in the products, and the cleansing and conditioning performance characteristics of the products.

The materials also contain negative statements about both the Petitioner and the products.

2. Testimony On The Representations

At the Administrative Hearing, the Postal Service presented no witnesses with respect to the representations made by the materials. Petitioner presented the testimony of an expert in consumer marketing as well as several persons who had read the articles.

Dr. Carol Scott, at that time a Professor of Marketing at UCLA, testified that, in her expert opinion, the materials did not, when read in their entirety, represent that the products will stop hair loss in balding men or will cause the regrowth of hair on bald heads. She testified that the 1980 Sacramento Bee advertisement separated the general

populace from an "interested audience" because it required the reader to take an affirmative action, i.e., requesting information. Dr. Scott testified that this interested reader is not the ordinary, average person, but one who is a more sophisticated and discerning consumer who could read the materials at his or her own speed, would be likely to read all of the material, and would process the information in light of his or her experiences with baldness.

Using this audience as the appropriate target for Petitioner's materials, Dr. Scott testified that the materials are not persuasive in a commercial sense: They provide skeptical information on the products, and do not promise that the products will have any effect on baldness. Her expert conclusions were that the

materials did not represent that the products will stop hair loss in balding men or will cause the regrowth of hair on bald heads. Her expert conclusion was that the materials, read as a whole, do not make the representations alleged in the Complaint.

Several lay witnesses testified to the representations made to them by the materials. All of these witnesses were in the interested group defined by Dr. Scott. These witnesses, who included an attorney, a psychiatrist, an anesthesiologist and a dentist, all testified that the materials did not represent or suggest to them that the products will stop hair loss in balding men or cause the regrowth of hair on bald heads.

3. Product Efficacy

If the evidence supports the allegations of the Postal Service that the materials represent that the products will stop hair loss in balding men and will cause the regrowth of hair on bald heads, the question becomes whether those representations are false. The Postal Service offered one witness, Dr. Karl Kramer, a dermatologist, to testify that in his opinion the products would not stop hair loss in balding men or cause the regrowth of hair on bald heads.

Dr. Kramer testified that polysorbate 60, the chief ingredient in the hair and scalp cleanser/conditioner, would remove dihydrotestosterone (a hormone which is believed to be the cause of male pattern baldness), from the hair follicle where it exerts its effect. He also testified

that he was unaware of there being any placebo effect with baldness products. He testified that he did not know whether, as a matter of fact, the products would stop hair loss in balding men or cause the regrowth of hair on bald heads.

Seventeen product users testified that as a result of using the products, they either had a lessened hair fallout or had some hair regrowth after using Petitioner's products. In addition, photographs of nine witnesses, showing their scalps before and after using Petitioner's products were introduced into evidence. The after photographs showed an equal amount of hair, or more hair, than the before pictures.

ARGUMENT

A. The Standard of Review

The standard of review of this case is whether the Postal Service decision is supported by substantial evidence. This court held in Universal Camera Corp. v. NLRB, 430 U.S. 474, 476 (1951) that substantial evidence

> ... is more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.

B. Evidence on The Representations

In determining what representations are made in Petitioner's materials, the finder of fact is not to review them

> with a lawyer's eye to 'fine spun distinctions", but with an eye to their overall effect upon the average reader.

American Image Corp. v. USPS, 370 F. Supp. 964, 966 (S.D.N.Y., 1974); M.K.S.

Enterprises v. USPS, 459 F. Supp. 1180, 1187 (E.D.N.Y., 1978). Furthermore, the meaning of advertising representations must be determined from consideration of the advertisement in its totality, not merely selected excerpts thereof. Donaldson v. Read, 333 U.S. 178 (1948); Vibra-Brush Corp. v. Schafer, 152 F. Supp. 461 (S.D.N.Y., 1957) vacated on other grounds 256 F.2d 681 (2nd Cir., 1958).

The courts have recognized that the definition of "average reader" must be adjusted to the realities of each particular case, and that whether an advertisement contains a false representation must be determined by its impact on those to whom it is directed. Van Dyne Advertising Agency, Inc. v. USPS, 371 F. Supp.

1373, 1376 (S.D.N.Y., 1974). In M.K.S. Enterprises v. USPS, supra, 459 F. Supp. at 1187, the court held that:

> ... while there is in each advertisement language which in different contexts might support the agency's findings, when viewed as an integral part of each of these advertisements the same language yields a different meaning. Just as an advertiser may not avoid the prohibitions of 39 U.S.C. 3005 by artfully assembling from true statements as advertisement that as a whole is misleading, the Postal Service cannot invoke its authority under this section unless the overall effect of an advertisement is to mislead the ordinary consumer. (Emphasis in original)

Thus, consistent with the case law and the testimony of Petitioner's marketing expert, the representations made in the materials must be viewed through the eyes of the group to whom they are directed - those interested in baldness, not the ordinary, average consumer. Dr.

Scott's expert testimony confirmed by the reader witnesses, was that the materials, when read as a whole and in context, did not make the representations alleged in the Complaint.

The District Court found (App. p. 29):

> ...the Judicial Officer, presumably a highly educated attorney with great intellectual capacity, cannot assume that his perceptions reflect the average consumer's in relation to evaluating the advertising of a specific product. This is not to say that he cannot draw upon his own experience to determine the "natural and probable result of the use of advertising expressions." Standard Oil Co. v. FTC, 577 F.2d 653, 659 (9th Cir. 1978). But, where unopposed expert testimony is received on an issue best interpreted by an expert, and no reason appears to doubt the credibility of the witness, or the accuracy of the opinion, the fact testified to by the expert should be deemed established under the Federal Rules of Evidence. Franklin Supply Co. v. Tolman, 454 F.2d 1059, 1071, (9th Cir., 1971).

The District Court found that Dr. Scott was competent to testify to the

representations made by the materials (as did the Administrative Law Judge, Initial Decision, p. 7). The District Court also found that the testimony of the lay witnesses was erroneously ignored by the Postal Service. The Court found (App. p. 33) that:

> The Judicial Officer fails to note, however, that these four witnesses are all consumers who came to New Generation through the advertising materials in question. To reject their testimony entirely because they may be more sophisticated than the average New Generation consumer is to ignore the only testimony presented by persons actually responding to the advertising materials. The Judicial Officer simply cannot turn his back to actual consumer testimony and substitute instead his own opinion of how consumers would react. Standard Oil Co. v. FTC, supra; M.K.S. Enterprises v. USPS, supra.

The District Court also addressed the issue of the use of the word "will" in the Complaint (Op., p. 4). The

Complaint alleged that New Generation "will stop hair loss in balding men" and "will cause the regrowth of hair on bald heads" (see, Initial Decision, p. 2). In the District Court, the Postal Service contended that the use of the word "will" in the Complaint really meant "may". The District Court rejected the Postal Service argument that the use of the word "will" in the Complaint was merely semantical, and held that the Postal Service Complaint should be read as written.

After reviewing the testimony of Dr. Scott, the materials and the testimony of the lay witnesses, the District Court found that a reasonable mind would not find relevant evidence adequate to support the allegations made by the Postal

Service, and ruled that substantial evidence did not exist to support the Postal Service decision on the representations issue.

The Court of Appeals reviewed this matter de novo. In discussing the use of the word "will" in relation to the word "may", the Court stated (App., p. 12) that the District Court's distinction between the words "will" and "may" ignores the most logical reading of the Complaint. The Court stated (App. pp. 13-14) that

> The fact that a promoter of a product does not claim that the product will work for every consumer does not absolve the promoter from liability under 39 U.S.C. 3005 where, as the Postal Service Judicial Officer found here, the promotional materials suggest that the product will produce beneficial results for a substantial percentage of consumers.

This begs the issue, however, of what the Complaint actually stated. If the

Postal Service had meant "may" instead of "will", surely it would have used that word in the Complaint and not claimed for the first time in the District Court that it meant something other than what the Complaint stated.

The Court of Appeals also found that the overall impression of the materials was that the products will cause regrowth of hair and will stop hair loss, finding it immaterial that disclaimers and expressions of skepticism were present in the materials. Even the Court of Appeals acknowledged, however, that the materials did not represent that the products will work for all people (App., p. 13).

Without citing any authority, the Court of Appeals held that the Judicial Officer was free to ignore the testimony

of Petitioner's expert and form his own conclusions as to what representations were made by the material. This holding ignores the reality of the testimony of the expert. The Court of Appeals, again without citing any authority, held that the Postal Service was free to ignore the testimony of the lay witnesses who were in the group of consumers to whom Petitioner's products were directed.

Petitioner submits that the District Court correctly applied the law to the facts of this case in undertaking its review of whether substantial evidence supported the Postal Service decision. The Court of Appeals, without undertaking a de novo review of the facts in the case as it alleged it had done, simply held that the Judicial Officer could decide for himself the import of

Petitioner's materials and was free to ignore the relevant, competent, admissible evidence to the contrary. Petitioner submits that the Court of Appeals clearly committed error in reversing the District Court on this issue.

Petitioner believes that under Supreme Court Rule 17, the right of both the Judicial Officer and the Court of Appeals to ignore competent and relevant evidence in favor of reaching their own unfounded decision presents an important issue which has, to the best of Petitioner's knowledge, not been settled by this Court but should be settled by this Court.

C. Evidence on Falsity

The only witness offered by the Postal Service at the hearing was Dr. Karl

Kramer, a Miami, Florida dermatologist who testified that, in his expert opinion, the products will not cause the regrowth of hair on bald heads or stop hair loss in balding men. His opinion was not based upon any actual experience with the products, but was based upon what he believed to be the consensus of informed medical opinion. Based upon his testimony alone, the Judicial Officer determined that the representations alleged in the Complaint, having been found by him to be made, were false.

The District Court noted that the Judicial Officer correctly found that Dr. Kramer's testimony established the consensus of informed medical opinion and that this was prima facie evidence

that New Generation will not stop excessive fallout or cause the regrowth of hair in balding males (App., p. 35) the Court then noted that the burden fell to produce some rebuttal evidence in order to eliminate the prima facie presumption, again citing F.R.E. 301.

The District Court found that Petitioner had successfully defeated the prima facie presumption by presenting five pieces of evidence (App., pp. 37-38):

> First, they elicited testimony from Dr. Kramer that ... Polysorbate 60 may dissolve di-hydrotestosterone (DHT), which Dr. Kramer testified is currently thought to cause (male pattern baldness), in the follicular canal and scalp. (A.R. 114-115, 120-124, 143-144). ... Second, CPR presented the controlled Setala/Schreck-Purola studies testing the effects of Polysorbate 60 on hair growth. ... Third, although not required to admit such testimony, 39 CFR 952.18(f), numerous law witnesses testified as to New Generation efficacy, and this evidence was considered by both the ALJ and the Judicial Officer. A.R. 992, 737-740.

* * *

The fourth piece of evidence ... was photographic. The AL admitted, and the Judicial Officer considered, photographs of five lay witnesses apparently showing a regrowth of hair. See A.R. 712-714, 715-719. ... Finally, the number of complaints received by the USPS about a product can constitute some evidence of its efficacy. USPS v. Stimpson, 515 F. Supp. 1149, 1151 (D. Fla., 1981). ... In the present case there is no evidence that, after over 6,000 orders, a single complaint has been received by the USPS about New Generation.

The Court concluded (App. pp. 42-43):

Considering these five pieces of evidence together, the Court finds that the Judicial Officer erred as a matter of law in finding that (Petitioner) did not sufficiently rebut the presumption raised by Dr. Kramer's initial testimony. (Citn. omitted) At this point, the prima facie presumption disappeared and the burden of proof remained with the USPS to show that New Generation is not effective in ameliorating MPB. Id. This burden was not met because, on rebuttal testimony, Dr. Kramer acknowledged the results represented. A.R. 120-124, 143-144. Thus, substantial evidence does not support the Judicial Officer's finding that New Generation's representations are in fact false.

The Court of Appeals completely ignored the well-reasoned analysis of the District Court. It simply stated that Dr. Kramer's opinion as to the consensus of informed medical opinion constituted, in and of itself, substantial evidence to support the Postal Service finding that Petitioner's representations were false, citing Research Laboratories, Inc. v. United States, 167 F.2d 410, 416-417 (9th Cir., 1948). That case is, however, inapposite here.

That case was a civil seizure brought pursuant to the provisions of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 301, et seq. In such a case, the standard of proof is by a preponderance of the evidence, not substantial evidence as it is here. Thus, evidence that may have been sufficient to support a conclusion in an FDA civil seizure action is not necessarily sufficient to support a conclusion of substantial evidence in a

Postal Service case.

As the District Court pointed out (App., p. 43) the standard for determining factual issues under the Food, Drug and Cosmetic Act is different from that under the Postal Service statutes. As contrasted with the new drug provisions of the Food, Drug and Cosmetic Act, 21 U.S.C. 321(p) and 355, where the absence of objective tests is sufficient to demonstrate the ineffectiveness of a drug, the District Court correctly pointed out that it is the burden of the Postal Service in USPS cases to show the product's ineffectiveness. The District Court noted that this holding was especially significant in light of this Court's decision in Reilly v. Pinkus, 338 U.S. 269 (1949).

The Court of Appeals also determined that Dr. Kramer's testimony was substantial evidence notwithstanding the anecdotal and testimonial evidence offered by various users of appellee's products, citing Simeon Management Corp. v. FTC, 579 F.2d 1137, 1143-44 (9th Cir., 1978). However, the reference in the Simeon case is to the Food, Drug and Cosmetic new drug standards which, as the District Court pointed out, are not the standards applicable to Postal Service cases.

The Court of Appeals, again relying on the Research Laboratories case, stated that in light of Dr. Kramer's testimony with respect to the informed medical consensus, the Postal Service was not required to present evidence of clinical

tests of Petitioner's products. As pointed out above, the Research Laboratories case is inapposite here.

Furthermore, the Court of Appeals decision totally ignores the District Court's discussion of certain evidence and that evidence itself in evaluating the findings of the Postal Service. The Court of Appeals gives only passing attention to the testimony of the users, all of whom the District Court found to have male pattern baldness (App., p. 38) and competent to testify as to hair regrowth (App., p. 39). The District Court further noted Dr. Kramer's testimony that he knew of no study which has found a placebo effect occurring in male pattern baldness (Id.) The Court of Appeals also paid no attention to the photographic evidence.

Most importantly, the Court of Appeals ignored the District Court's discussion of burden of proof and the distinction between the burden of going forward and the burden of proof. Petitioner submits that the District Court was correct in its analysis of the factual evidence and that the Court of Appeals was clearly incorrect.

An important question, to date unanswered by this Court, is what proof need be presented by the Postal Service in a case brought pursuant to 39 U.S.C. 3005 to support a finding that a representation is false in fact. This statute does not deal with standards of general recognition of and adequate and well-controlled investigations as does the Food, Drug and Cosmetic Act, supra.

Concomitant with this issue is what is the burden of proof as distinguished from the burden of going forward in these cases, and at what point, and with what type of evidence, does the prima facie presumption end and cause the Postal Service to present evidence of actual ineffectiveness as opposed to theoretical ineffectiveness.

There are extremely important issues that have not been, but should be, settled by this Court. See, Sup. Ct. Rule 17. Thus, these issues are ripe for a determination by this Court on this Petition for a Writ of Certiorari, and the Petition should be granted. Petitioner respectfully requests that this Petition be granted and this case be heard on its merits.

APPENDIX

The Appendix to this Petition,

consisting of the two Postal Service decisions and the two court decisions is filed herewith.

Dated: October 3, 1986

Respectfully submitted,

GELLER & BOZEMAN

By _____
Jay H. Geller

Attorneys for Petitioner
California Pacific Research, Inc.

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APPENDIX OF OPINIONS TO PETITION FOR A WRIT OF CERTIORARI TO THE NINTH CIRCUIT COURT OF APPEALS

Jay H. Geller
GELLER & BOZEMAN
2049 Century Park East
Suite 1200
Los Angeles, CA 90067

Attorneys for
Petitioner
California Pacific
Research, Inc.

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UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

CALIFORNIA PACIFIC RESEARCH, INC.,	)	No.85-1727
Plaintiff-Appellee	)	DC No. CV R-83-172(BRT)
vs.	)	
	)	MEMORANDUM
UNITED STATES POSTAL SERVICE,	)	FILED JULY 10, 1986
Defendant-Appellant	)	

Appeal from the United States District Court for the District of Nevada

Hon. Bruce R. Thompson, U.S. District Judge, Presiding

Argued and submitted December 13, 1985

Before: Duniway and Tang, Circuit Judges and Hupp, District Judge

In the administrative decision on review here, the United States Postal Service found that appelle California Pacific Research, Inc., in violation of 39 U.S.C. 3005, falsely represented in promotional materials that its shampoo

and scalp cleanser products stop excessive hair loss and cause regrowth of hair on men with male pattern baldness. Certain orders restricting appellee's use of the mails followed. California Pacific Research sought judicial review of the decision. The District Court vacated the Postal Service's false representation orders. The District Court concluded that there was no substantial evidence in the administrative record to support the Postal Service's finding that California Pacific Research, Inc. had represented that its products will reduce hair loss and cause regrowth of hair in men with male pattern baldness. Further, the District Court concluded that, even if substantial evidence supported the Postal Service's finding that such representations had been made about the

efficacy of appellee's products, there was no substantial evidence in the administrative record to support the Postal Service's ruling that the representations were false. We hold that Postal Service's decision was supported by substantial evidence on both counts and, accordingly, reverse the decision of the District Court.

I.

FACTS

Appellee California Pacific Research markets a "hair improvement program" consisting of "New Generation Hair and Scalp Cleanser" and "New Generation Shampoo." In the marketing operation on review here, appellee promoted its products in the Sacramento area by placing an advertisement in the Sacramento Bee that sought to induce interested consumers

to write or call appellee for more information regarding its products. The newspaper advertisement began: "BALDING? maybe New Generation has the answer for you! If you missed our Sacramento Bee & Union articles regarding male pattern baldness, we will be more than happy to mail copies to you." Upon request, appellee mailed to interested consumers copies of newspaper articles, together with a product order form that included promotional information prepared by appellee.

The materials mailed by appellee to interested consumers included photocopies of newspaper articles that reported successful results obtained by a group of Sacramento men who had used appellee's products. Copies of two newspaper articles included in appellee's

promotional materials reported that, in appellee's testing of the product on approximately 60 men, "(a)fter some six to 10 months of use, about 80 percent report at least some progress in covering the shining parts of their heads." Appellee also appended its own commentary to photocopies of one newspaper article, noting that of the scores of men who had tested appellee's product, "(n)early 100 percent have reported a slowdown or stopping of hair fallout." In addition, the product order form included in the promotional materials stated that 80 percent of the test participants experienced regrowth of hair and almost 100 percent of the participants realized an end to abnormal hair "fall-out" within 3 to 4 weeks.

In the administrative hearing, appellee introduced testimony from Dr.

Carol A. Scott, an associate professor of marketing at UCLA's Graduate School of Management, to the effect that appellee's promotional materials, when read by an interested consumer, did not represent that appellee's products will cause the regrowth of hair or stop hair loss in balding men. Appellee also introduced testimony to the same effect from "lay readers" of appellee's promotional materials. The Postal Service did not introduce expert testimony on the issue of what appellee's promotional materials represented to interested consumers.

The Postal Service, however, did introduce expert witness testimony regarding the purported efficacy of appellee's products. Dr. Karl Jules Kramer testified that in his opinion appellee's products could not cure male

pattern baldness and that the informed consensus of the medical community was that the active ingredient in appellee's products did not provide an effective treatment or cure for male pattern baldness. Appellee California Pacific, on the other hand, introduced lay testimony from 17 users of appellee's products, along with "before and after" photographs of several users of the products. Appellee also offered the testimony of an expert in pharmaceutics, Berton E. Ballard. However, Dr. Ballard's testimony did little to advance appellee's position and, indeed, did not contradict Dr. Kramer's assertion that the informed consensus of the medical community was that the active ingredient in appellee's products did not provide an effective treatment for male pattern baldness.

II.

PROCEDURAL HISTORY

The Postal Service's administrative complaint charged that appellee falsely represented that its products (a) "will stop hair loss in balding men"· (b) "will cause the regrowth of hair on bald heads"; and (c) "will strengthen and thicken new hair as it grows back on bald heads." The administrative law judge found that appellee had falsely represented that its products will cause the regrowth of hair on bald heads, but ruled that appellee had not represented that its products will stop hair loss and strengthen and thicken new hair in men with male pattern baldness. In an administrative appeal, see 39 C.F.R. 952.25(a), 952.26(c), the Postal Service Judicial Officer upheld the ALF's finding that appellee

had falsely represented that its products will stop excessive hair loss in balding men. (The Judicial Officer had authority to conduct de novo review of the issues. See Containerfreight Transportation v. I.C.C., 651 F.2d 668, 670 (9th Cir. 1981).) Accordingly, the Postal Service issued false representation orders under 39 U.S.C. 3005(a)(1), (2), conditioned in part upon a final determination of whether the impact of appellee's promotion had been restricted to the Sacramento area.

Following the Postal Service's final ruling, appellee sought judicial review of the decision. The District Court granted California Pacific Research's motion for summary judgment and vacated the Postal Service's false representation orders. The District

Court concluded that "substantial evidence does not support the Judicial Officer's findings that (1) (California Pacific Research) represents that it will stop excessive hair loss in balding men; (2) (California Pacific Research) represents that it will cause regrowth of hair; (3) and that these claims are false as a matter of fact."

III. STANDARD OF REVIEW

The only question presented in this Appeal is whether there is substantial evidence to support the Postal Service's decision that appellee falsely represented that its products will stop excessive hair loss and will cause regrowth of hair in men with male pattern baldness. Because the question posed in this appeal is identical to that presented in the trial court -- i.e., whether substantial

evidence existed in the administrative record to support the Postal Service's decision -- this court's review of the administrative record is essentially the same as that undertaken by the District Court. Cf. Stone v. Heckler, 761 F.2d 530, 532 (9th Cir. 1985)("(T)he statutory scheme mandates a full review of the facts by our court and an independent determination as to whether the (agency's) findings are supported by substantial evidence.")

IV. WAS THERE SUBSTANTIAL EVIDENCE TO SUPPORT THE POSTAL SERVICE'S FINDING THAT APPELLEE REPRESENTED THAT ITS PRODUCTS WILL STOP EXCESSIVE HAIR LOSS AND CAUSE REGROWTH OF HAIR?

As an initial matter, it is of no importance here that the Postal Service's administrative complaint alleged that appellee represented that its products "will stop hair loss," while the

Postal Service ultimately found only that appellee represented that its products will stop "excessive" hair loss. The plain meaning of the administrative complaint was that appellee allegedly represented not that its products would stop all hair loss, but rather that its products would stop excessive hair loss.

Appellee's promotional materials in themselves constitute substantial evidence that appellee represented that its products will stop excessive hair loss and will cause the regrowth of hair of hair in men with male pattern baldness. Yet appellee argues that, contrary to the assertion in the administrative complaint that appellee represented that its products "will" stop hair loss and "will" cause regrowth of hair, appellee's

promotional materials merely suggest that appellee's products "may" benefit some individuals in some cases. This argument, however, ignores the most logical reading of the administrative complaint: that appellee had represented that its products will cause the cessation of excessive hair loss and will cause the regrowth of hair in a substantial number of men with male pattern baldness. The representations fairly jump out from appellee's promotional materials, which describe an 80% percent success rate in hair regrowth among the scores of men who had tested the products and an almost 100% success rate in the cessation of excessive hair loss. The fact that a promoter of a product does not claim that the product will

work for every consumer does not absolve the promoter from liability under 39 U.S.C. 3005 where, as the Postal Service Judicial Officer found here, the promotional materials suggest that the product will produce beneficial results for a substantial percentage of consumers. Moreover, given that the overall impression left by appellee's materials was that appellee's products will stop excessive hair loss and cause regrowth of hair, it is immaterial that the materials also included references to some mild disclaimers or expressions of skepticism about the efficacy of the products.

Further, it is also immaterial here that appellee introduced the only expert testimony on the effect that appellee's promotional materials would have on appellee's target audience. Appellee's

reliance on Franklin Supply Co. v. Tolman, 454 F.2d 1059, 1071 (9th Cir., 1972), is misplaced, for in the instant action the question of what overall effect appellee's promotional materials had on the interested consumer did not require evidence from an expert witness. The ALJ and the Postal Service Judicial Officer were free to form their own conclusions -- without reference to appellee's expert witness testimony -- as to whether or not appellee in its promotional materials represented that its products would stop hair loss and cause regrowth of hair in men with male pattern baldness.

Substantial evidence means "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." Richardson v. Perales, 402

U.S. 389, 401 (1971), quoting Consolidated Edison Co. v. NLRB, 305 U.S. 197, 229 (1938). Appellee's promotional materials in themselves constitute substantial evidence of the Postal Service's findings that appellee represented that its products will stop hair loss and cause regrowth of hair in a substantial percentage of men with male pattern baldness.

V. WAS THERE SUBSTANTIAL EVIDENCE TO SUPPORT THE POSTAL SERVICE'S FINDING THAT APPELLEE'S REPRESENTATIONS ABOUT ITS PRODUCTS WERE FALSE?

Dr. Kramer testified that it was his opinion that appellee's products could not cure male pattern baldness. He further testified that it was the informed opinion of the medical community that the active ingredient in appellee's products was not an effective cure or treatment for male pattern baldness. There was,

therefore, substantial evidence to support the finding that appellee's representations about the efficacy of its products were false. See Research Laboratories, Inc. v. United States, 167 F.2d 410, 416-17 (9th Cir. 1948). Contrary to the conclusion of the District Court, the administrative record demonstrates that Dr. Kramer never wavered from his conclusion that appellee's products would not stop excessive hair loss or cause regrowth of hair in men with male pattern baldness. Dr. Kramer was unequivocal in his rejection of the various theories put forward by appellee to support its position concerning the efficacy of its products.

In light of Dr. Kramer's testimony, there was substantial evidence to support the Postal Service's decision,

notwithstanding the anecdotal and testimonial evidence offered by various users of appellee's products. See Simeon Management Corp. v. F.T.C., 579 F.2d 1137, 1143-44 (9th Cir. 1978). Moreoever, since Dr. Kramer testified that it was his opinion that appellee's products were not an effective cure for male pattern baldness and, further, that the informed consensus of the medical community was that the active ingredient in appellee's products would not provide an effective treatment for male pattern baldness, the Postal Service was not required to present evidence of clinical tests of appellee's products. See Research Laboratories v. United States, 167 F.2d at 416-7.

Because there was substantial evidence to support the Postal Service's decision

that appellee falsely represented that its products will stop excessive hair loss and cause regrowth of hair in men with male pattern baldness, the Postal Service's administrative decision must be upheld. Accordingly, we reverse the District Court's order and remand the matter with instructions to enter judgment consistent with the determination that substantial evidence supports the Postal Service decision.

REVERSED AND REMANDED.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEVADA

CALIFORNIA PACIFIC RESEARCH, INC., a Nevada corporation,

Plaintiff,

vs.

UNITED STATES POSTAL SERVICE,

Defendant.

Civil R-83-172-BRT

SUMMARY JUDGMENT

Plaintiff, California Pacific Research, Inc. (CPR), markets a product known as "New Generation Hair and Scalp Cleanser" (New Generation) which is designed to combat male pattern baldness (MPB) by preserving and regenerating hair growth in balding men. On August 14, 1980, CPR's president, Robert Murphy, placed an advertisement in the Sacramento Bee newspaper soliciting inquiries by mail about New Generation. A.R. 180.[1/]

(Text of advertisement appears at A.R. 977). Upon receipt of an inquiry, Murphy responded by mailing reprints of newspaper articles concerning New Generation combined with an order blank. A.R. 180-181.

Based upon these occurrences the defendant, United States Postal Service (USPS), brought an administrative complaint against CPR. The complaint alleges that the advertisement, and Murphy's responses thereto, constitute a scheme to obtain money or property through the mail by means of a materially false representation in violation of 39 U.S.C. 3005. After a hearing before Administrative Law Judge (ALJ) Quentin E. Grant on October 1 and 2, 1981, an initial decision was rendered on April 9, 1982 against CPR on count "b" of the complaint. A.R.

975-993. An administrative appeal was taken by both parties from this decision pursuant to 39 C.F.R. 952.25. A.R. 916. On May 13, 1983, USPS Judicial Officer James Cohen reviewed the parties' exceptions and filed an opinion substantiating essentially all of Judge Grant's findings. A.R. 726-758. Judge Cohen reversed the ALJ on count "a" of the complaint, however, finding CPR also in violation of 39 U.S.C. 3005 as to that count.

Accompanying his decision, Judge Cohen issued postal order 83-85, effective May 13, 1983, detaining CPR's mail for inspection at the Sacramento, California and Sparks, Nevada post offices pursuant to 39 U.S.C. 3005(a)(1) and (2). A.R. 759. After inspection, Judge Cohen ordered mail identifiable with New

Generation returned with the stamp "Return to Sender; Order Issued Against Addressee for Violation of False Representation Law." Id. As a result of this order CPR no longer received inquiries at the addresses listed, cuasing irreparable injury to the company in terms of both its credibility and productivity. Affidavit of Robert Murphy at 1. (Attached to file document #2). CPR's complaint herein seeks review of Judge Cohen's decision and reinstatement of its right to use the mail for marketing New Generation. The case is presently before the Court on cross-motions for summary judgment.

This Court's jurisdiction to review the Judicial Officer's decision is found in the Administrative Procedures Act (APA), 5 U.S.C. 551 et seq. and 701 et seq. at 702. M.K.S. Enterprises, Inc.

v. USPS, 459 F. Supp. 1180, 1182 (D.N.Y. 1978). The standard of review is directed by 706(2)(E) and is limited to "determining whether there is, considering the record as a whole, substantial evidence to support (the Judicial Officer's) findings of fact, and whether he has committed errors of law." Baslee Products, Inc. v. USPS, 356 F. Supp. 841, 844 (D.N.J. 1973), see also Kurzon v. USPS, 539 F.2d 788, 794 (1st Cir. 1976), accord Mark Eden v. Lee, 433 F. 2d 1077 (9th Cir. 1970) (applying substantial evidence standard to predecessor statute of 39 U.S.C. 3005). In accordance with these authorities, the Court has thoroughly reviewed the entire administrative record and considered the pleadings and oral arguments presented in determining that the decision of Judicial Office Cohen is not supported by

substantial evidence.

PRODUCT REPRESENTATIONS

In order to find that CPR violated 39 U.S.C. 3005, the Judicial Officer was required to make a two-fold analysis: (1) whether the representations alleged are in fact made by CPR's advertising materials; and (2) that these representations are in fact false. Reilly v. Pinkus, 338 U.S. 269 (1949). The Judicial Officer found that CPR's advertising materials made the representations alleged in the administrative complaint regarding hair loss and regeneration. A.R. 729-731, 756. Specifically, he found that CPR represented New Generation will stop excessive hair loss in balding men and will cause the regrowth of hair on bald heads. Id. These two findings are not supported by substantial evidence. CPR's advertising materials make it abundantly clear that the product works only for some users.

Thus, while there is substantial evidence that CPR represents New Generation will stop excessive hair loss or cause regrowth in some cases, there is absolutely no evidence in the record that it is represented to do this in all cases as alleged in the complaint.[2]

Defendant's position that this distinction is merely "semantical" and that "will" equates to "may" is unfounded. Had defendant alleged in the administrative complaint that CPR merely represents New Generation "may" work, Dr. Kramer's testimony could not have supported the Judicial Officer's decision. Dr. Kramer admitted that the theory behind New Generation may produce the results represented. A.R. 993. In addition, his statement that the consensus of medical opinion concluding that New Generation will not work does not

deny the possibility, regardless of the probability, that it will work. A.R. 64-66. Thus, defendant must necessarily take the position that CPR's advertising materials represent New Generation "will", not "may", stop excessive fallout and cause regeneration of hair in males suffering from MPB.

In determining that representations "a" and "b" of the administrative complaint are made by CPR's advertising materials, the Judicial Officer erred as a matter of law. He disregarded both the expert testimony of Dr. Scott and the lay testimony of the user witnesses, substituting instead his own judgment of how a person of average intelligence and education would view the advertising materials. A.R. 731, 741-42. The consensus of case law of this issue is best stated by Judge Knapp: "such advertisements are not be

viewed with a lawyer's eye to 'fine spun distinctions' but with an eye to their overall effect upon the average reader." American Image Corporation v. USPS, 370 F. Supp. 964, 966 (D.N.Y. 1974), see also N. Van Dyne Advertising Agency, Inc. v. USPS, 371 F. Supp. 1373, 1376 (D.N.Y. 1974); Baslee Products Corporation v. USPS, 356 F. Supp. 841, 844 (D.N.J. 1973); Stein's v. Pilling, 256 F. Supp. 238, 243 (D.N.J. 1966).

> This test (Judge Knapp's) is, however, more easily stated than applied, because it requires the agency or reviewing court to evaluate an advertisement not by hard logical analysis of its parts but by forming an impression of the whole, in an attempt to gauge the overall effect of the advertisement upon the largely undefined yet apparently naive and uncritical "ordinary" reader.

M.K.S. Enterprises v. USPS, 459 F. Supp.

1180, 1184 (D.N.Y. 1978).

Judicial Officer Cohen, presumably a highly educated attorney with great intellectual capacity, cannot assume that his perceptions reflect the average consumer's in relation to evaluating the advertising of a specific product. This is not to say that he cannot draw upon his own experience to determine the "natural and probable result of the use of advertising expressions." Standard Oil Co. v. FTC, 577 F.2d 653, 659 (9th Cir. 1978). But, where unopposed expert testimony is received on an issue best interpreted by an expert, and no reason appears to doubt the credibility of the witness, or the accuracy or inherent probability of the opinion, the fact testified to by the expert should be deemed established under the Federal Rules

of evidence.[3] Franklin Supply Co. v. Tolman, 454 F.2d 1059, 1071 (9th Cir. 1971).

Judge Cohen's findings that Dr. Scott's testimony was (1) ambiguous; (2) confusing; and (3) not worthy of reliance are not supported by substantial evidence. This Court is in the same position as Judge Cohen to weigh the credibility of Dr. Scott's testimony since he did not view her examination. As Dr. Scott's resume shows, she is a highly qualified expert in marketing, consumer behavior consumer research, and advertising. A.R. 714-a through 714-f, A.R. 298-304. Her analysis of each document separately and then in combination was both thorough and specific. See A.R. 308-316. She explained that the ordinary consumer of New Generation would be a motivated

person since the advertisement requires him to write for more information. A.R. 343. Logically, she testified that people who are motivated or interested in a topic area pay more attention when reading advertising materials concerning the topic area than the ordinary consumer. Putting all this together, she concluded that plaintiff's advertising materials do not convey to the average New Generation consumer that the product will stop excessive hair loss in balding men or cause the regrowth of hair on bald heads. A.R. 320-322.

In addition to Dr. Scott's testimony, several lay-witnesses-consumers of New Generation testified to their impressions of CPR's advertising materials. See testimony of Dr. Malcolm J. McKillop at

A.R. 225-6; testimony of Dr. Lew Smith at A.R. 393; testimony of Mr. William B. O'Neal at A.R. 536; and testimony of Mr. James Cose at A.R. 552. The consensus of this testimony is that the witnesses perceived CPR's advertising materials to say that New Generation will stop excessive hair fallout and cause regrowth of hair for some, but not all, users of the product. Again, Judge Cohen rejected this evidence out of hand, stating only that "(t)he user-witnesses who testified in this proceeding do not necessarily represent the viewpoint of the ordinary reader at whom these materials were directed (because they) ... may reasonably be considered more sophisticated than the ordinary interested reader of (CPR's) materials." A.R. 742. Judge Cohen cites no authority for this proposition. Id.

The Judicial Officer fails to note, however, that these four witnesses are all consumers who came to New Generation through the advertising material in question. To reject their testimony entirely because they may be more sophisticated than the average New Generation consumer is to ignore the only testimony presented by persons actually responding to the advertising materials. The Judicial Officer simply cannot turn his back to actual consumer testimony and substitute instead his own opinion of how consumers would react. Cf. Standard Oil Co. v. FTC, 577 F.2d 653, 659 (9th Cir. 1978); M.K.S., supra.

Based on the foregoing the Court holds that substantial evidence does not support the Judicial Officer's findings regarding CPR's advertising materials. The expert and consumer testimony, both unopposed by

the defendant, made clear that the ads do not guarantee that excessive hair fallout will stop or that regrowth will occur. In addition, a review of the materials shows that no statement is made that New Generation will stop excessive fallout or cause regrowth in all cases as alleged in the Complaint. See advertisement at A.R. 638 (Blading? Maybe New Generation has the answer for you!)(emphasis added); advertisement at A.R. 643(b) ("I've seen living proof that it works. I only hope I'm in that 70 to 80 percentile that is successfully growing hair"). Accordingly, the Court finds no substantial evidence to support the Judicial Officer's finding that CPR's advertising materials represent New Generation to stop excessive fallout in all balding men and to cause regrowth of hair on all

balding heads. A.R. 756, 742.

PRODUCT EFFICACY

Even if substantial evidence existed to support the Judicial Officer's finding that CPR represents New Generation to stop excessive hair loss and cause regrowth, substantial evidence does not exist to support the finding that these claims are false. Several statements in both Judge Grant's and Judge Cohen's decisions show that the burden of proof on the issue of falsity was impermissibly shifted to CPR in violation of 39 U.S.C. 3005, which places the burden on the USPS. See A.R. 746-747, 993. Although the burden of production may be shifted to CPR once prima facie evidence has been established by the USPS, the burden of proof never shifts. F.R.E. 301, see also Cosvetic Labs, et al., P.S. Docket No. 8/180, P.S.D.

of December 22, 1982 at 14. (Quoted at A.R. 746).

The Judicial Officer correctly found that Dr. Kramer's testimony established the informed medical consensus as to Polysorbate 60, the active ingredient in New Generation. A.R. 745-747. This is prima facie evidence that New Generation will not stop excessive fallout or cause regrowth of hair in balding males. Cosvetic Labs, supra. The burden then shifted to CPR to produce some evidence rebutting, and thus eliminating, the prima facie presumption. F.R.E. 301, Legille v. Dann, 544 F.2d 1, 5-6 (D.C. Cir. 1976). This was successfully done by plaintiff here. Plaintiff consented several pieces of evidence which disputed

the informed consensus of medical opinion. First, they elicited testimony from Dr. Kramer that Dr. Ballard's theory of how New Generation works may well be valid. A.R. 603-04. This is because Polysorbate 60 may dissolve di-hydrotestosterone (DHT), which Dr. Kramer testified is currently thought to cause MPB, in the follicular canal and scalp. A.R. 114=115, 120-124, 143-144. Second, CPR presented the controlled Setala/Schreck-Purola studies testing the effects of Polysorbate 60 on hair growth. See A.R. 665, 691. Although these studies are of limited value, they constitute some evidence of the efficacy of Polysorbate 60. A.R. 266-270. Third, although not required to admit such testimony under 39 C.F.R. 952.18(f), numerous lay witnesses testified as to New Generation's efficacy, and this evidence

was considered by both the ALJ and the Judicial Officer. A.R. 992, 737-740.

The lay witness testimony, in each case, sufficiently established that the user was suffering from MPB and not from the other relatively rare (in men) scalp diseases of alopecia areata or telogen effluvium. A.R. 20-22. This is because in each case the witness lost hair over a long period of time and had a history of baldness in his family. Id., see also A.R. 360; 367-368; 380-381; 391-392 (witness actually diagnosed as suffering from MPB); 403-404; 408-409; 428-429; 449-450; 466-467; 488-489; 517-518; 531-532; 550; 575-576 (witness actually diagnosed as suffering from MPB). These witnesses, as a whole, testified that they experienced success in both stopping excess hair loss

and regrowing new hair by using New Generation. See id., et seq. While Dr. Kramer testified that lay observation of hair loss is unreliable, he did not contend that a patient was not competent to observe new hair growth. A.R. 27. Thus, the testimony of the lay witnesses should have been considered as some evidence of the product's efficacy.

The fourth piece of evidence presented by plaintiff to rebut the informed consensus of medical opinion was photographic. The ALJ admitted, and the Judicial Officer considered, photographs of five lay witnesses apparently showing a regrowth of hair. See A.R. 712-714, 715-719. The Judicial Officer upheld the ALJ's refusal to accord probative value to the photographs based on a lack of lighting, combing, or placebo controls. A.R. 740. One witness, who had been diagnosed as

suffering from MPB, testified that the lighting in each set of photographs was identical, and it is clear from the photos that the combing was also identical. A.R. 389, 390-391, compare A.R. 713 and 714 with A.R. 715 and 716 (exhibit 8 with exhibits 4 and 5). As to controlling for a placebo effect, this was not shown by defendant to be necessary. Dr. Kramer testified that MPB is hereditary and thus not psychological. A.R. 23. In addition, he testified that he knows of no study which has found a placebo effect occurring in MPB. A.R. 628. Thus, the photographs constituted some evidence of New Generation's efficacy.

Finally, the number of complaints received by the USPS about a product can constitute some evidence of its

efficacy. USPS v. Stimpson, 515 F. Supp. 1149, 1151 (D.Fla. 1981). In Stimpson the Court held that the USPS failed to show the respondent's envelope-stuffing system did not deliver the promised rewards:

> In fact the Government's evidence indicates Ms. Stimpson may have many happy customers. Ms. Stimpson is presently receiving approximately 84 pieces of mial a day. In the past month the Postal Service has received 36 inquiries about her operation. Thirty-six inquiries out of approximately 2,520 mailings is a very low complaint ratio. The Government has certainly not presented evidence indicating the ratio is abnormally high.

Id. In the present case there is no evidence that, after over 6,000 orders, a single complaint has been received by the USPS about New Generation. A.R. 988. In fact, the USPS began investigation of CPR based upon a postal inspector's viewing of the Sacramento Bee advertisement, not as a result of a complaint. Memorandum

in support of motion for stay of enforcement of Postal Service Order 83-85 at 1-2. (Attached to document # 4).

Considering these five pieces of evidence together, the Court finds that the Judicial Officer erred as a matter of law in finding that CPR did not sufficiently rebut the presumption raised by Dr. Kramer's initial testimony. See Legille, supra. At this point, the prima facie presumption disappeared and the burden of proof remained with the USPS to show that New Generation is not effective in ameliorating MPB. Id. This burden was not met because, on rebuttal testimony, Dr. Kramer acknowledged that New Generation may product the results represented. A.R. 120-124, 143-144. Thus, substantial evidence does not support the Judicial Officer's finding that New Generation's

representations are in fact false.

It is troublesome that both the ALJ and the Judicial Officer seem to endorse the statement of Dr. Kramer that the theory behind New Generation "may or may not be true, but you have to prove it." A.R. 604, see A.R. 993, 746. Although the law pertaining to the proposed marketing of new drugs under 21 U.S.C. 321(p), 355(d) and (e) states that the absence of objective tests would be sufficient to demonstrate the inefficacy of a new drug, this is clearly not the law relating to proceedings under 39 U.S.C. 3005. Kurzon v. USPS, 539 F.2d 788, 793 (1st Cir. 1976). In these proceedings, the burden is on the USPS to show the product's inefficacy. Id., 39 U.S.C. 3005(a). As pointed out by Judge Clark in Peak Laboratories v. USPS:

> To say that the Postal Service could stop all advertisements which report tests or studies from entering the mails by producing an expert witness who would do no more than express an opinion disagreeing with the reported results, would give it far too great a license to pick and choose what may be delivered through the mails.

556 F.2d 1387, 1341 (5th Cir. 1977)(concurring opinion). This is especially true in light of the United States Supreme Court's admonition in Reilly v. Pinkus that "in the science of medicine, as in other sciences, experimentation is the spur of progress. It would amount to condemnation of new ideas without a trial to give the Postamaster General power to condemn new ideas as fraudulent solely because some cling to traditional opinions with unquestioning tenacity." 338 U.S. 269, 274 (1949).

Finally, it is also troublesome that

the USPS has spent a great deal of time and taxpayers' money protecting consumers from a product which has generated no complaints, is not harmful to users, and which appears to help some sufferers of MPB alleviate what they perceive as a traumatic physicial condition. President Johnson, on recommending passage of 39 U.S.C. 3005 to Congress, stated that "only the Federal Government can have effective authority over interstate mail order sales. Only the exercise of that authority can protect the buyer and legitimate seller alike against loss and injury." H.R. 235, 90th Cong., 2d Sess., 1968 U.S. Code Cong. & Ad. News at 4293. Here, there is no evidence of loss or injury. It is undisputed that all consumers who are unhappy with New Generation receive a full refund of their purchase price. A.R. 181. This number has

run about eight percent. Id. Also, New Generation's only active ingredient is a harmless detergent or emulsified. A.R. 37, 593-594. Finally, the use of New Generation does not deter a user from seeking treatment from a physicial since, according to Dr. Kramer, no generally accepted cure exists. A.F. 49. Based on these facts, it is difficult to see how any of the consumer protection policies underlying 35 U.S.C. 3005 are furthered by the decision under review. See generally, H.R. 235, supra.

In conclusion, the Court holds that substantial evidence does not support the Judicial Officer's findings that: (1) New Generation represents it will stop excess hair loss in balding men; (2) New Generation represents it will cause regrowth of hair on bald heads;

and (3) that these claims are false as a matter of fact. Accordingly, summary judgment should be granted to plaintiff and Postal Service orders 83-85 and 84-16 should be vacated.

In consideration of the premises,

IT HEREBY IS ORDERED, ADJUDGED AND DECREED that false representation Order No. 83-85 issued on May 13, 1983 by James A. Cohen, Judicial Officer of the United States Postal Service, and False Representation Order No. 84-16 issued on March 8, 1984 by Acting Judicial Officer Joan B. Thompson of the United States Postal Service, are hereby vacated and set aside.

DATED January 7, 1985.

s/Bruce R. Thompson
UNITED STATES DISTRICT JUDGE

FOOTNOTES

1/ References are to the Administrative Record.

2/ The administrative complaint alleges that CPR represents New Generation "will stop hair loss in balding men" and "will cause the regrowth of hair on balding heads." It does not allege that CPR represents New Generation "will stop hair loss in some balding men" or "will cause regrowth of hair on some bald heads." A.R. 728.

3/ The Federal Rules of Evidence control in Postal Service hearings. 39 C.F.R. 952.18(a).

OFFICE OF ADMINSTRATIVE LAW JUDGES

In the Matter of the Complaint Against	)	April 9, 1982
NEW GENERATION CALIFORNIA PACIFIC RESEARCH INC., Post Office Box 22750 at Sacramento, CA 95822 and Post Office Box 2570 at Sparks, NV 89431	)	P.S. Docket No. 11/152

INITIAL DECISION

The Complaint filed herein charges that Respondent is in violation of 39 U.S.C. 3005 in connection with the sale of certain hair products. The Complaint specifically alleges that Respondent violates the statute by selling these products - NEW GENERATION HAIR AND SCALP CLEANSER and NEW GENERATION SHAMPOO - through the mails by means of materially false representations, made in advertising and promotional materials that:

"a. NEW GENERATION HAIR AND SCALP CLEANSER and NEW GENERATION SHAMPOO will stop hair loss in balding men; and

b. NEW GENERATION CLEANSER AND SHAMPOO will cause the regrowth of hair on bald heads; and

c. NEW GENERATION CLEANSER AND SHAMPOO will strengthen and thicken new hair as it grows back on bald heads.

Respondent's Answer denied all allegations of the Complaint.

A hearing was held in San Francisco, California, and several evidentiary depositions and affidavits were thereafter taken and filed.

The parties have filed proposed findings of fact, conclusions of law, briefs, and reply briefs, all of which have been considered in arriving at this decision. To the extent indicated proposed findings and conclusions have been adopted. Otherwise they have been rejected as irrelevant, immaterial, or not supported by the evidence.

FINDINGS OF FACT

1. Respondent, California Pacific Research, Inc., is a Nevada Corporation, a mail order business, that sells through the mails NEW GENERATION HAIR AND SCALP CLEANSER and NEW GENERATION SHAMPOO, the products involved in this proceeding (Stipulations 1-5; CX-2a-2e, 3a, 3b; Tr. 159). Respondent seeks remittance for such products through the mails (CX-2c, 3e).

2. Respondent initially attracts attention to these products by means of the following newspaper advertisement (CX-1):

Copy filed separately.

3. Persons responding to this advertisement receive from Respondent reprints of articles concerning Respondent and the products involved which

appeared in The Sacramento Bee, The Sacramento Union, and the Suttertown News, together with an advertisement headed "RESULTS, SO FAR, OF OUR CONTINUING HAIR IMPROVEMENT PROGRAM" and an attached order blank for the products (CX-2a), (b), (c), 3(d), p. two). These advertising materials are reproduced below.

Copies filed separately.

4. In furnishing the above article excerpts to persons inquiring about the New Generation products, Respondent adopted them as promotional material for the sale of such products (Tr. 178).

5. Respondent's president, Robert E. Murphy, Jr., testified that Respondent represents in its advertising and promotional material that a certain percentage of users with male pattern baldness (MPB) would experience less hair fallout and

would possibly revert to a state of normal fallout. He denied that Respondent makes any representation that the products will stop hair loss or cause regrowth of hair on bald heads or will strengthen and thicken new hair as it grows back on bald heads (Tr. 183, 184).

6. Carol A. Scott, Ph.D., an associate professor of marketing at the Graduate School of Management, University of California at Los Angeles testified for Respondent as an expert in the interpretation of advertising. According to Dr. Scott on her direct examination, Respondent's advertising is directed at an audience with a balding problem; it is uniformly optimistic but very cautious (Tr. 309); its information would be processed very carefully by bald or balding men; it

is relatively unpersuasive (Tr. 326); and neither individually, nor in combination, do the various advertising and promotional items make the representations alleged in the Complaint (Tr. 310-331).

7. On cross-examination Dr Scott said that her negative answers on direct examination to question as to whether Respondent makes the representations alleged in the Complaint meant that she would not interpret the advertising and promotional material as saying that all users would get the results (Tr. 306, 346). She stated that an interested reader would interpret the "RESULTS, SO FAR, ***" part of the advertising, supra, (CX-2(c), 3(d), p. 3) as representing that 80% of users have experienced regrowth of hair and that 100% have stopped abnormal hair fallout (Tr. p. 344, 345) and that it would encourage such readers to order the product on

the strength of the hope that they would be lucky enough to be among the 80% who have experienced regrowth of hair (Tr. 344).

8. Dr. Scott acknowledged that inclusion of negative or skeptical reports in Respondent's promotional material could reinforce the positive messages therein by adding credibility (Tr. 347-349).

9. As of the time of the hearing Respondent has received about 6000 orders for the products (Tr. 332) and about 470 requests for refund (Tr. 181).

10. In late 1979 and early 1980 Mr. Murphy conducted a non-scientific study of the products involving 50 or 60 people. The results of this study as self-reported by participants are the basis for the

percentages of success in stopping excessive hair loss and producing new hair growth set forth in Respondent's advertising material (Tr. 201, 206; CX-2(c)). Respondent did not keep careful records of the study. Mr. Murphy tried to get as many people with creditable reputations to say that the product worked (Tr. 206).

11. A total of 17 users of the product, not counting Mr. Murphy, testified at the hearing, or by deposition, concerning results obtained by using Respondent's products. Sixteen of the 17 reported the halting of excessive hair loss, regrowth of hair, strengthening and thickening of new hair, or all of such results. These user witnesses represented a broad cross-section of professions and occupations, from physicians and scientists to lawyers, bankers, media personalities, government officials, law enforcement

officials, and businessmen.

12. Karl Jules Kramer, M.D., testified for Complainant. Dr. Kramer is board-certified in both internal medicine and dermatology. He is engaged in the private practice of dermatology in Miami, Florida. He keeps current in that field by reading medical journals, attending seminars and meetings concerned with his specialty, and, as a member of the staff of Jackson Memorail Hospital, attending weekly meetings. In his practice, Dr. Kramer deals with patients complaining of hair and scalp disorders. His professional experience and knowledge qualifies him to describe the elements of a valid scientific study, including the design and conduct thereof (Tr. 13-17; CX-6).

13. Based on Dr. Kramer's testimony I find as follows:

Human hair is dead, or inert, material

composed primarily of protein. The living part of the hair is called the hair follicle. Hair follicles of scalp hair go through the following cycle: (a) the anagen, or growth, phase lasting approximately four years; (b) the catagen phase, a short period during which the follicle grows smaller; (c) the telogen, or resting, phase, lasting about four months, during which the hair rests, i.e., the hair follicle does not grow but the hair remains in the scalp; (d) return to the growth phase, the old hair falling out as the new hair grows.

The human scalp is continuously producing new haird and hairs are continuously being shed. Taking the average person, approximately 85% of the hair follicles are growing at any one time and 15% are resting. Average loss is between 50 and 100 hairs per day (Tr. 18, 19).

Male pattern baldness (MPB) is the most common cause of excessive hair loss and the appearance of baldness (no visible hairs on the scalp). It occurs in upwards of 80% of men by the time they reach 60 or 70 years and may begin before the age of 20.

Hereditary (genetic) predisposition together with hormonal influences are the major causes of MPB. The hair follicles that are genetically predetermined to be lost change testosterone from the blood-stream into another hormone called dihydrotesosterone (DHT). Over a period of time DHT destroys the hair follicle.

MPB does not produce total hair loss over the entire scalp. A fringe of hair invariably remains in the back the hair follicles in that area not having the cpapcity to change testosteron into the follicle-destructive DHT.

Dirty scalps are not a cause of MPB (Tr. 152).

14. NEW GENERATION HAIR AND SCALP CLEANSER (hereinafter referres to as the cleanser) is composed of purified water and Polysorbate 60 (CX-5). Polysorbate 60 is used primarily as an emulsifier in products designed to remove oils or oily materials (Tr. 37).

15. NEW GENERATION SHAMPOO (hereinafter referred to as the shampoo) has the ingredients: purified water, Amphoteric-2, Cocamide DEA, COcamido-propyl Betaine, Citric Acid, Methyl Paraben and Propyl Paraben (CX-4).

Amphoteric-2 is widely used in shampoos as an electrically neutral chemical. Cocamide DEA, widely used in the cometics industry, is a derivative of coconut oil and has an oily consistency. Cocamido-propyl betaine is a similar derivative of

coconut oil and is also contained in many shampoos. Citric acid is generally used as a preservative in cosmetic products. Nethyl paraben and propyl paragen are also used as preservatives. All of these ingredients, or closely related chemicals, are commonly used in widely available shampoos (Tr., 35, 36).

16. Dr. Kramer's opinion, conforming to the informed medical consensus, is that neither Polysorbate 60 (the active ingredient of the cleanser) nor the shampoo, nor the two products used together, will prevent excessive hair loss or cause new growth of hair on bald scalps (Tr. 45, 63, 64, 66). Dr. Kramer's research did not reveal any contrary opinion supported by valid scientific studies (controlled, double-blind) such as would be required to substantiate the efficacy of the products to stop excessive hair loss and cause

regrowth of hair (Tr. 38-45).

17. Cholesterol is a building block of steroid hormones, including testosterone but the only glands in the body able to make testosterone from cholesterol are the testes and the adrenal glands (Tr. 120). It is possible that polysorbate 60 will remove cholesterol from the scalp (Tr. 143), but since cholesterol is not converted to testosterone in the scalp its removal is not related to MPB (Tr. 118-120).

18. It is a general principle in medicine that if it is suggested to a patient that a preparation will produce in him a certain result, even if the preparation has no real pharmacologic effect, it is more likely that such result will be achieved than if that suggestion had not been made. This is known as the placebo effect (Tr.

49, 50). It was suggested to the users of Respondent's products who gave evidence in this matter that use of the products would result in reduced hair loss and growth of new hair.

19. Results of the use of a preparation self-reported by patients, or users, are not accorded validity in the scientific community (Tr. 51). The results of the use of Respondent's products introduced into evidence through user-witnesses were self-reported. Photographs introduced in support of the testimony of such witnesses were subject to too many variables, such as differences in lighting and differences in combing, to furnish persuasive support for the testimony although some photographs appear to show more hair after, than before use of the products (Tr. 207-209).

CONCLUSIONS OF LAW

1. The meaning of advertising representations is to be judged from a consideration of an advertisement in its totality and the impression it would most probably create in ordinary minds. Donaldson v. Read Magazine, 333 U.S. 178 (1948); Vibra-Brush Corp. v. Schaffer, 152 F. Supp. 461 (S.D.N.Y. 1957); Borg-Johnson Electronics v. Christenberry, 169 F. Supp. 746 (S.D.N.Y. 1959). Express representations are not required. It is the net impression which the advertisement is likely to make upon purchasers to whom it is directed which is important, and even if an advertisement is so worded as not to make an express representation, if it is artfully designed to mislead those responding to it the mail fraud statutes are applicable. G.J. Howard v. Cassidy, 162 F. Supp. 568. See also Virginia State Board of

Pharmacy v. Virginia Citizens Council, 425 U.S. 743 (1976).

The ultimate impression on the reader results not only from what is stated but also from what is reasonably implied therefrom. Vibra-Brush Corp. v. Schaffer, supra; Aronberg v. Federal Trade Commission, 132 F.2d 165 (7th Cir. 1942).

2. (a) Applying the foregoing principles to Respondent's advertising and promotional material, I find that Respondent makes the representation that New Generation Scalp Cleanser and Shampoo will cause retrowth of hair on bald heads. This is so obviously the main thrust of such material that it requires no detailed discussion. The text is cleverly laced with notes of skepticism and reports of i lated failures, but I find their tendency to be the enhancement of credibility for the affirmative statements of efficacy of the

product to grow hair.

This representation is material in that its obvious effect is to influence readers to purchase the product.

(b) I do not find that Respondent's advertising and promotional material makes in any serious or material manner the other representations alleged in the Complaint. There is only one mention of a user experiencing the strengthening and thickening of new hair, the emphasis being on new hair. With respect to loss of hair the representation is that the product will stop excessive loss of hair, not that it will stop hair loss as alleged in the Complaint. There was no motion by Complainant to conform pleadings to proof. I do not consider it fair and appropriate to amend the Complaint at this juncture.

3. Neither expert nor lay testimony is required to interpret advertisements

under 39 U.S.C. 3005. Vibra-Brush v. Schaffer, supra. The record here is replete with both kinds of such testimony. Insofar as that testimony was to the effect that Respondent's advertising and promotional materials do not make the representation found above, I reject it as flying in the face of the obvious express and implied thrust of such materials, the fact that Respondent has received at least 6000 orders for the products, and also as contrary to plain common sense. Even Respondent's expert, Dr. Scott, acknowledged on cross-examination that interested readers of such material would interpret it to mean that large percentages of users had experience regrowth of hair (80%) and cessation of abnormal hair loss (100%) and would be encouraged to order the products on the strength of the hope that they would be among the lucky ones. She also

made the significant acknowledgement that the negative, or skeptical, content of the material could reinforce the positive message by adding credibility thereto.

Respondent says that Vibra-Brush, supra, was reversed by the Circuit Court of Appeals (256 F.2d 681) and, therefore, cannot be relied on as support for discounting lay and expert testimony on interpretation. The decision was not reversed. It was withdrawn by the higher court on a technicality having no relationship to the points for which the District Court decision is repeatedly cited.

4. Based on the testimony and opinions of Complainant's medical expert witness, Dr. Kramer, conforming to the informed medical consensus, I find that the representation made by Respondent as to regrowth of hair on bald heads is false in

fact.

Dr. Kramer was well-qualified by education, experience, and continuing awareness of relevant, current medical and scientific literature and thinking to express such opinions. It is reasonable to assume that a scientifically valid study showing that topical application of polysorbate 60 to bald or balding male scalps will cause regrowth of hair would be widely reported in reputable professional journals. Evidence of such a study has not been shown to exist. The Setala-Schreck Purola study (CX-7) relied on by Respondent, did not involve the same combination of ingredients as the product in question here. Therefore, I can attach no materiality or weight to it. Further, there is no scientifically valid support for its underlying theory that cholesterol is converted in the scalp to testosterone.

5. Expert opinion testimony need not be based upon tests of the particular product in issue to constitute sufficient evidence of false advertising representations. Reilly v. Pinkus, 338 U.S. 269, 274 (1949); Original Cosmetics Products, Inc. v. Strachan, 459 F. Supp. 496 (S.D. N.Y. 1978) aff'd 603 F.2d 214, Table, (2nd Cir. 1979), cert den. 444 U.S. 915 (1979); Skinny Suit, P.S. Docket No. 3/44 (P.S. Dec., 2/19/76, p. 6).

6. A finding of falsity can be based on the testimony of an expert witness whose testimony is in accord with the consensus of informed medical or scientific opinion when there is no contradictory evidence which is said to be in accord with such a consensus of opinion. Athena Products, Ltd. P.D. Docket No. 7/99 (P.S. Dec., 6/16/81, p. 33); Standard Research,

P.S. Docket No. 7/78 (Initial Decision, December 13, 1979); Standard Research, P.S. Docket 7/48 (Initial Decision, August 31, 1979); Modern Age Products, Inc., p.S. Docket No. 5/102 (P.S. Dec., June 29 1977; Initial Decision, April 6, 1977); Nutrient Laboratories, P.S. Docket No. 5/48 (Initial Decision, November 17, 1976).

There is no such contradictory evidence in the record of this case.

7. Respondent says that knowledge in the field of dermatology concerning the mechanism of hair loss in male pattern baldness and how hormones actually affect hair follicles has not been "crystallized in the crucible of experience" and that in these circumstances representations in Respondent's promotional materials cannot be found to be false, citing American School of Magnetic Healing v. McAnnulty, 187 U.S. 94 (1902); Reilly v. Pinkus, 338 U.S. 269, 174 (1949); Original Cosmetics Products, Inc., v. Strachan, supra. As

interpreted in Reilly v. Pinkus, supra, McAnnulty set aside a postal fraud order pointing out that there were two widely held schools of opinion as to whether the mind could affect bodily diseases, and that scientific knowledge had not advanced to the point where an actual intent to deceive could be attributed to one who asserted either opinion. Thus there was "no exact standard of absolute truth by which to prove the assertion false and a fraud." At best, testimony either way was held to be no more than "opinion" in a field where imperfect knowledge made proof "as of an ordinary fact" impossible.

The instant case bears no resemblance to McAnnulty. There are not at the present time, and consequently, there are not reflected in this record, two widely held schools or opinions as to whether a scalp

product, such as Respondent's, containing polysorbate 60 will cause regrowth of hair. Only one real school of opinion - the medical consensus established through Dr. Kramer - has been shown here. The linchpin of that consensus is that cholesterol is not converted in the scalp to testosterone. Therefore, removal of cholesterol from the scalp by polysorbate 60 has no influence on hair fallout or regrowth. It follows that McAnnulty and the other cases cited by Respondent do not require rejection of Dr. Kramer's opinion or evidence of testing of the product by Dr. Kramer.

8. Although the witness-users of Respondent's product who testified at the hearing appeared to be honest and attempting to tell the truth, their accounts were purely anecdotal, not rising to the level of valid, scientific proof for the important claim at issue. The "before and after"

photographs are not conclusive because of variables involved, such as lighting and combing. Their claimed use of the product was not scientifically supervised. No accurate records thereof were maintained. There were no controls established. The results they reported were consistentwith a possible placebo effect, particularly since they were told before use of the product that it might produce new growth.

9. The fact that the placebo effect may occur in the case of some users does not support the efficacy of the product or the truthfulness of Respondent's representations. Stauffer Laboratories v. F.T.C., 343 F.2d 75 (9th Cir. 1965); Original Cosmetics Products, Inc. v. Strachan, supra; Wilmont Products, P.S. Docket No. 6/46 (P.S. Dec., 1979).

10. The testimony of Dr. Ballard,

Respondent's expert in pharmacy and pharmaceutics, fell far short of establishing the efficacy of Respondent's product to achieve the results represented or of effectively countering Dr. Kramer's opinions. Summed up, Dr. Ballard's testimony consisted principally of a theory (based on the Schreck-Purola 1976 study involving mice and not shown to have involved a preparation the same as Respondent's) that polysorbate 60 might be efficacious.

11. It may be that Respondent's product will produce the results represented. Dr. Kramer acknowledged this. But in the present state of medical and scientific knowledge there is no reliable support for such claims such as to overcome the contrary consensus by Dr. Kramer.

12. Disclaimers are ineffective to rebut misrepresentations. Gottlieb v.

Schaffer, 141 F. Supp. 7 (1956); Cates v. Haderlein, 189 F.2d 369 (1951).

13. Respondent's offer of a refund to dissatisfied purchasers does not overcome the effects of making false representations. Borg-Johnson Electronics v. Christenberry, supra.

14. Respondent is engaged in a scheme to obtain money through the mail by means of materially false representations in violation of 39 U.S.C. 3005. Accordingly, an order in the form attached should be issued against Respondent.

signature
Quentin E. Grant
Administrative Law
Judge

JUDICIAL OFFICER

In the Matter of the Complaint) Against NEW GENERATION CALIFORNIA PACIFIC RESEARCH, INC., P.O. Box 22759 at Sacramento, CA 95822-0759 and P.O. Box 2570 at Sparks, NV 89431-2570	) May 13, 1983) P.S. Docket No. 11/152

POSTAL SERVICE DECISION

Respondent has appealed from the Initial Decision of an Administrative Law Judge which holds that, with regard to the advertising and sale of the products New Generation Hair and Scalp Cleanser and New Generation Shampoo, Respondent is engaged in a scheme to obtain money or property through the mail by means of a materially false representation in violation of 39 U.S.C. 3005.

BACKGROUND

On July 8, 1981, the Consumer Protection Division, Law Department, United States Postal Service (Complainant) filed a

complaint allegeing the Respondent was selling hair products through the mail, marketed under the trade names New Generation Hair and Scalp Cleanser and New Generation Shampoo, by means of false representations in violationof 39 U.S.C. 3005. Specifically, Paragraph 3 of the Complaint alleges that Respondent represents that:

"a. NEW GENERATION HAIR AND SCALP CLEANSER and NEW GENERATION SHAMPOO will stop hair loss in balding men; and

b. NEW GENERATION CLEANSER AND SHAMPOO will cause the regrowth of hair on bald heads; and

c. NEW GENERATION CLEANSER AND SHAMPOO will strengthen and thicken new hair as it grows back on bald heads."

Paragraph 4 of the Complaint alleges that the above representations "are materially false as a matter of fact."

Respondent filed an Answer denying all of the allegations in the Complaint. At a

hearing before an Administrative Law Judge, expert testimony was presented by Karl J. Kramer, M.D. (for Complainant), and by Burton E. Ballard, Doctor of Pharmacy, and Carol A. Scott, PhD. (for Respondent). Respondents also presented a number of other witnesses, including Robert E. Murphy, Jr., Respondent's president, and lay users of the products at issue.

At the hearing, the Administrative Law Judge granted a Motion to Amend the Complaint to include an additional address and received stipulations by the parties, which primarily concerned Complainant's test purchse of the products. After the hearing, the testimony of other lay product users and additonal testimony of Dr. Kramer was taken by deposition. Also after the hearing, the Administrative Law

Judge rejected Respondent's offer to introduce selected portions of transcribed testimony by Dr. Ilona Schreck-Purola and Postal Inspector Michael Powers, who had testified in Cosvetic Labs., et al., P.S. Docket No. 8/160, et al. However, he received in evidence affidavits and photographs of several witnesses who had testified in the present proceeding.

On April 9, 1982, the Administrative Law Judge issued an Initial Decision which found that Respondent represents that New Generation Scalp Cleanser and Shampoo will cause regrowth of hair on bald heads and that this representation is both material and false. However, he did not find "that Respondent's advertising and promotional material makes in any serious or material manner the other representations alleged in the Complaint" (I.D. at 14). With

specific regard to the allegation in Paragraph 3a of the Complaint that Respondent's product "will stop hair loss in balding men," the Administrative Law Judge found that Respondent represents "that the product will stop excessive loss of hair, not that it will stop hair loss as alleged in the Complaint. There was no motion by Complainant to conform pleadings to proof. I do not consider it fair and appropriate to amend the Complaint at this juncture." (Id.).

Both parties have appealed the Initial Decision to the Judicial Officer and have filed Appeal, Reply and Response Briefs. Respondent has also filed a Motion to Reopen the Hearing in the event that a False Representation Order is issued for the purposes of determining which mail is in response to the August 16, 1980 advertisement in the Sacramento Bee (CS-1), and

in order to adduce additional testimony with respect to Conclusion of Law No. 2(a) of the Initial Decision. By Order dated July 1, 1982, the motion was held in abeyance pending the issuance of this decision.

The exceptions filed by each party, and Respondent's motion, are discussed separately below.

I. RESPONDENT'S EXCEPTION TO THE INITIAL DECISION

Respondent has appealed from 13 Findings of Fact and 14 Conclusions of Law which are discussed, in turn, below. Exceptions have been combined, where appropriate.

1. Exceptions to Findings of Fact Nos. 1, 2, and 3

These findings state that Respondent sells New Generation Hair and Scalp Cleanser and New Generation Shampoo through the mail, that attention is initially attracted to these products by means of the

newspaper advertisement admitted into evidence as CX-1, and that persons responding to this advertisement receive reprints of newspaper articles concerning the products, together with an advertisement headed "Results, So Far, Of Our Continuing Hair Improvement Program" and an order blank, all of which have been admitted into evidence as CX-2(a), (b), (c) and 3(c), page 2.

Respondent contends that the Administrative Law Judge's use of the present tense in these findings to describe Respondent's activities is improper, because the referenced newspaper advertisement only ran one time and, therefore, only attracted attention to these products for a limited period. Respondent further contends that the record is unclear as to the particular period during which it used any of the referenced promotional materials,

citing its motion to reopen the hearing. In this regard, Complainant argues that it is entitled to a presumption that Respondent's current advertisements are substantially similar to those used at the time of the hearing, since Respondent did not provide information regarding its current advertisements as requested in prehearing interrogatories.

While the record does not disclose how long advertisement CX-1 has been in use (cf. Tr. 108), Robert E. Murphy, Jr., Respondent's president, testified that, as of the hearing, he still used the newspaper articles as promotional materials in marketing the products (Tr. 212). Even if the advertisement and promotional materials have since been discontinued, this would not moot the proceeding or preclude the issuance of a false representation order, since present customers could still

be influenced by the prior representations. Profit and Churches of the New Octave, P.S. Docket No. 6/5 (P.S.D. Oct. 14, 1977); Cf. Cosvetic Laboratories, et al., P.S. Docket No. 8/160, et al. (P.S.D. On Motion for REcon., Dec. 22, 1982) and Raymond Milo, P.S. Docket No. 12/168 (P.S.D. on Motion for Clarification of Amendment to False Representation Order, July 16, 1982).

Findings of Fact Nos. 1 through 3 are accepted as describing the method by which Respondent has advertised and promoted its products. The duration and continuing impact, if any, of these advertising and promotional practices are addressed separately, infra.

2. Exceptions to Findings of Fact Nos. 7 and 8

These findings concern the expert testimony of Carol A. Scott Ph.D., an associate professor of marketing at the

Graduate School of Management, University of California at Los Angeles. Respondent objects to the Administrative Law Judge's characterization of this testimony.

A review of the record discloses that Dr. Scott's testimony, as a whole, was ambiguous and confusing. Her conclusions regarding whether Respondent's promotional materials made the representations at issue are therefore of little value. The Administrative Law Judge, and the Judicial Officer on review, may form their own conclusions, without reference to testimony, regarding whether the representations were made or implied. Vibra-Brush v. Schaffer, 152 F. Supp. 461 (S.D.N.Y. 1957); Beneficial Corp. v. F.T.C., 542 F.2d 611, 617 (3rd Cir. 1976), cert. denied, 430 U.S. 983 (1977).

While the Administrative Law Judge's findings are selective and may not

accurately track Dr. Scott's testimony in all respects, the findings need not be disturbed in view of the present determination, based on a review of the record, that this witness's conclusions are unpersuasive, and that testimony is not necessary to determine whether a representation is made. Accordingly, Respondent's exceptions are rejects.

3. Exception to Finding of Fact No. 8

This finding states that "As of the time of the hearing Respondent has received about 6,000 orders for the products (Tr. 332) and about 470 requests for refund (Tr. 181)." Respondent contends that this finding is irrelevant to the issue in this case and may be misleading. This finding accurately reflects Mr. Murphy's testimony as to the total number of orders for the products as of the time of the hearing. Nonetheless, it does not

affect the disposition of this case. Therefore, it will not be considered.

4. Exception to Finding of Fact No. 10

This finding states, in part, that "a non-scientific study" by Respondent during late 1979 and early 1980 is "the basis for the percentages of success in stopping excessive hair loss and producing new hair growth set forth in Respondent's advertising material." Respondent contends that the record does not support the finding that it represents its products as "producing new hair growth."

CX-2(c), cited by the Administrative Law Judge in support of his finding, represents that product users "have received 60 to 65 percent of the hair loss back within one year ... with noticeable hair growth beginning in approximately 8 to 12 weeks." Further, Respondent's advertisement in the Sacramento Bee, CX-1, ends

by inviting readers "to watch an upcoming PM Magazine feature on our successful approach to hair restoration" (emphasis added). While, as a technical matter, Respondent may claim that its products do not cause new hair growth, but rather permit growth as a result of their cleaning action, the net representation is that the use of the products will result in new hair growth. Accordingly, this finding is affirmed.

5. Exception to Finding of Fact No. 12

Respondent excepts to the portion of this finding which states that "In his practice, Dr. (Karl J.) Kramer (Complainant's expert witness) deals with patients complaining of hair and scalp disorders." Respondent contends that this statement is prejudicial and irrelevant because mal pattern baldness is not a "disease."

Dr. Kramer, a dermatologist,

specifically testified that "approximately 10 percent of my practice would involve hair problems, scalp diseases and balding" (Tr. 14, emphasis added). Accordingly, the quoted portion of Finding of Fact No. 12 is modified to read "In his practice, Dr. Kramer deals with patients complaining of hair and scalp disorders and balding." The finding that Dr. Kramer is experienced in hair and scalp disorders is not irrelevant to this proceeding, since he testified regarding the difference between male pattern baldness and disorders which also cause hair loss, and stated an opinion that one of the individuals who grew hair as a result of Respondent's products may have had one of these disorders (Tr. 31-32).

6. Exception to Finding of Fact No. 13

This finding, which is based on Dr. Kramer's testimony, discusses the nature

of hair, hair growth, and male pattern baldness. Respondent contends that the Administrative Law Judge "picked and chose" only those portions of Dr. Kramer's testimony which supported his ultimate decision.

In summarizing witnesses' testimony, the Administrative Law Judge was entitled to weigh that testimony and highlight those portions which he considered most persuasive. As the term implies, findings of fact are not intended as complete summaries of the record but only as brief statements of those portions of the record relevant to ultimate determinations of fact. Immigration and Naturalization Service v. Bagamasbad, 429 U.S. 24, 25 (1976). Cf. Athena Products, Ltd., P.S. Docket No. 7/99 (P.S.D. June 26, 1981). When reviewing these findings on appeal, the entire record is examined to determine the

propriety of the particular findings being challenged. Based on a review of Dr. Kramer's entire testimony, it is concluded that Finding of Fact No. 13 is consistent with the conclusions expressed by that witness regarding the point addressed.

Respondent also suggests that the Administrative Law Judge should have mentioned Dr. Kramer's lack of experience in hair and scalp research or with the products at issue. There was no need to do so. Expert opinion testimony is admissible even where not based on personal knowledge or testing of the specifi product. Research Labs. v. United States, 167 F.2d 410, 416 (9th Cir. 1948); Omnitronics, P.S. Docket No. 12/9 (P.S.D. Oct. 7, 1982); Athena Products Ltd., P.S. Docket No. 11/77 (P.S.D. June 21, 1982). moreover, Dr. Kramer was qualified as an

expert witness without objection from Respondent's counsel (Tr. 17-18). Accordingly, Finding of Fact No. 13 is affirmed.

7. Exception to Finding of Fact No. 16

Respondent excepts to the finding that "Dr. Kramer's opinion, conforming to the informed medical consensus, is that neither Polysorbate 60 (the active ingredient of the cleanser) nor the shampoo, nor the two products used together, will prevent excessive hair loss or cause new growth of hair on bald scalps."

Respondent contends that Dr. Kramer only testified that his "views" conform to the informed medical consensus and never testified as to his "opinions." The witness testified to his "views" (Tr. 66). No practical difference exists between "views" and "opinions." See Webster's Third New International Dictionary, 1582 (1961).

Respondent further contends that a finding of consensus cannot be based on Dr. Kramer's testimony alone. However, in this case, the consensus testified to by Dr. Kramer was also based on his review of the medical literature (e.g., Tr. 14, 38). Moreover, Respondent did not present any testimony disputing Dr. Kramer's characterization of the consensus (Cf. Tr. 261-262).

As noted, supra, the Administrative Law Judge did not allow testimony transcribed in another Postal Service proceeding, Cosvetic Labs., et al., supra, finding that it involved a product different from Respondent's. Respondent contends that by relying on Dr. Kramer's testimony regarding Polysorbate 60 in making Finding of Fact No. 16, the Administrative Law Judge "is using the testimony of Dr. Kramer on this point to support his

ultimate decision while at the same time finding that the study on which Dr. Kramer based his testimony is not relevant to the proceedings at hand" (Resp. Appeal Brief at 11). Dr. Kramer testified that his professional discussions regarding Polysorbate 60 were in connection with the other product, "Bio-Genesis" (Tr. 45-46).

It is concluded that the Cosvetic testimony offered by Respondent should have been admitted to the extent that it concerned the substance Polysorbate 60. Accordingly, all of the testimony given by Inspector Powers and Dr. Schreck-Purola in this proceeding have been reviewed.[1/] Only a small portion of Inspector Power's testimony clearly pertains to Polysorbate 60. According to his testimony, the Finnish doctor states that this substance stimulates cell division in the hair follicle and, with urea, loosens

subcutaneous tissue (Cosvetic Tr. 250). The only portions of Dr. Schreck-Purola's testimony relating to Polysorbate 60 appear at pages 552-553 and 557 of the Cosvetic transcript. This witness stated that Polysorbate 60 increases mitotic activity in the epdiermis. However, she stated that she did not know whether this substance could be identified as an emulsified.

This testimony is of questionable relevance to the present proceeding, since it is clear from the record that Respondent's claims for Polysorbate 60 are based on its properties as an emulsified and cleanser. Moreover, this testimony indicates that Bio-Genesis contains other allegedly active ingredients not relevant to Respondent's product (see Cosvetic Tr. 245). In any event, Bio-Genesis has been determined not to have been proven as effective in either stopping excessive hair loss due to male

pattern baldness or causing the regrowth of hair. Cosvetic Labs. et al., P.S. Docket Nos. 8/160 and cases consolidated therewith (P.S.D. July 22, 1982). Accordingly, Finding of Fact No. 16 is affirmed.

8. Exception to Finding of Fact No. 17

This finding states in part that "It is possible that Polysorbate 60 will remove cholesterol from the scalp ..., but since cholesterol is not converted to testosteronein the scalp its removal is not related to MPB (Male Pattern Baldness) ..." Respondent contends that it has never relied on the theory that Polysorbate 60 removes cholesterol from the scalp and that, therefore, this finding is not relevant.

The theory that Polysorbate 60 affects male pattern baldness by removing cholesterol in the scalp was advanced

in the studies published by Drs. Schreck-Purola and Setala. This theory is referenced in Respondnet's promotional materials and testimony (CX-2A, 30; Tr. 7, 41, 161-162, 197, 232). The evidence suggests that Respondent relied on the cholesterol theory set forth in the Finnish studies in developing and marketing the products. It also appears that this theory was abandoned at the hearing in favor of another, presented by Dr. Ballard, that Polysorbate 60 should be able to solubilize di-hydrotestosterone, which Dr. Kramer previously testified was ultimately the cause of male pattern baldness (Tr. 24, 260-262). However, this theory, according to Dr. Ballard's own testimony, is merely a hypothesis that has yet to find its way into the medical literature (Tr. 262). Accordingly, Respondent's argument is without merit.

9. Exceptions to Finding of Fact No. 18 and Conclusion of Law No. 9

The Administrative Law Judge found that suggesting a preparation will produce a certain result increases the likelihood of that result even where the preparation has no pharmacologic effect. This is the "placebo effect." It was also found that such suggestions were made to Respondent's witnesses. In Conclusion of Law No. 9, the placebo effect was held to be inadequate to support the efficacy of a product.

Respondent argues that the finding ignores qualifying testimony which limits applicability of the placebo effect in the case of hair growth preparations. Consideration of the qualifying testimony, it is contended, renders the finding irrelevant. Further, Respondent points out that only one user testified that he was told to expect results. Thus, Respondent contends the record does not support

the second part of Finding of Fact No. 18.

Dr. Kramer defined the placebo effect as the finding states (Tr. 49-50). Although on cross-examination Dr. Kramer admitted that he was unaware of studies and had no personal knowledge of the placebo effect with respect to hair growth preparations (Kramer Dep. 25, 40), the finding is not irrelevant. Dr. Kramer also explained that the placebo effect is one of the reasons studies on the efficacy of products are controlled (Kramer Dep. 40-41). Thus, the placebo effect, however it is defined, is relevant to the method by which the efficacy of a product is determined and, more importantly, the failure to control for the placebo effect is relevant to the weight given to evidence in this proceeding (See also Finding of Fact No. 19, infra).

Respondent correctly points out that

only one witness testified directly to suggestions that the product would restore hair. However, Respondent need not have specifically stated that its products would work in order to have suggested, either knowingly or unknowingly, that they would work. This is evident from the testimony of Malcolm J. McKillop, one of the user-witnesses, who stated that while the newspaper articles did not represent to him that the product would in fact work, he interpreted the articles as representing that "most likely in most cases it would (work) and I felt that I might be one of those who might be helped by it" (Tr. 225). (Cf. also Karsh Dep. 6).

While the testimony of the other user-witnesses does not justify an unqualified finding that Respondent made this suggestion in all cases, this is not to say that some of the witnesses were immune to a

placebo effect. It is possible that their perception of the results obtained was influenced by preconceptions regarding the products' effectiveness as a cleanser (see Nosler Dep. 11-12), by a personal relationship with Mr. Murphy (see Brannigan Dep. 5), by television publicity (see CX-3D, p. 2), or simply by a desire to grow hair. Nonethe less, the exception is sustained insofar as that portion of Finding of Fact No. 18 may be considered to relate to the direct testimony of more than one user. The disposition of the case is not affected, however, because the Administrative Law Judge found one of Respondent's representations to be false independent of the placebo effect.

Respondent excepts to Conclusion of Law No. 9 on the basis that the placebo effect has been discredited on the facts in this case and that it has never argued

that its product causes a placebo effect. Conclusion of Law No. 9 is a correct statement of the law, amply supported by the cases cited. While the record does not support a finding that Respondent's witnesses experienced a placebo effect, the Administrative Law Judge correctly concluded that such an effect would not validate claims of product efficacy.

10. Exception to Finding of Fact No. 19

The Administrative Law Judge found that the results testified to by Respondent's witnesses constituted self-reporting and that self-reporting by users is not accorded validity in the scientific community. Photographic evidence was also found to be subject to too many variables to be reliable. Respondent argues that such reports are given validity in the scientific community, that the results, while self-reported, are supported by the

photographs, and that the photographs are reliable.

The record supports the finding of the Administrative Law Judge (Tr. 51, 131). Further, lay testimonials are specifically excluded as proof of product efficacy by the Rules of Practice, 39 C.F.R. 952.18(f). The photographs, in addition to the testimony about varying conditions, suffer from the lack of controls employed during use of Respondent's product by witnesses. Even assuming that positive results are depicted, Respondent's failure to demonstrate that all of the test users were properly diagnosed (Tr. 61) and that its procedures eliminated other explanations for the witness's results, such as the placebo effect (Kramer Dep. 40-41), severely limits the probative value of the photographs. Accordingly, the Administrative Law Judge did not err

in refusing to accord probative value to the user reports and photographs.

11. Exception to Conclusion of Law No. 1

This conclusion sets forth the legal principles under which advertisements are evaluated in proceedings brought under 39 U.S.C. 3005. The conclusion restates the often-cited standard of Donaldson v. Read Magazine, 333 U.S. 178(1948), that an advertisement should be viewed from the standpoint of the "ordinary mind." Respondent finds a contradiction between the "ordinary mind" standard and the Administrative Law Judge's further statement that "it is the net impression which the advertisement is likely to make on purchasers to whom it is directed which is important." These two statements are not contradictory, but rather, supplement each other. The ultimate standard by which advertisements are judged for purposes of

these proceedings is the impression they would most probably create in the ordinary minds of those to whom they are directed. See Cates v. Haderlein, 189 F.2d 369 (7th Cir. 1951); Telex and twx Directory, P.S. Docket No. 13/6 (P.S.D. April 1, 1983). For purposes of this case, it is recognized that Respondent's promotional material was directed at those who are concerned about hair loss and, specifically, male pattern baldness.

Respondent also takes exception to the portion of this conclusion which states that "even if an advertisement is so worded as not to make an express representation, if it is artfully designed to mislead those responding to it, the mail fraud statutes are inapplicable." Respondent contends that the term "artfully designed" is not applicable because the newspaper articles which comprised a major

portion of the promotional activites were authored by others. While the conclusion that these articles were "artfully designed" may be justified (see infra), it is irrelevant to the disposition of this matter, since proof of intent is not necessary in order to find a violation of 39 U.S.C. 3005.

Finally, Respondent contends that the statement in this conclusion that "the ultimate impression on the reader results not only from what is stated but also from what is reasonably implied therefrom" is irrelevant. This statement correctly reflects the manner in which Respondent's promotional materials have been evaluated and is therefore relevant.

Accordingly, this conclusion is affirmed except as indicated.

12. Exception to Conclusion of Law 2(a)

This portion of Conclusion of Law No.

2 states, in part, that "Respondent makes the representation that New Generation Scalp Cleanser and Shampoo will cause re-growth of hair on bald heads. This is so obviously the main thrust of such material that it requires no detailed discussion." Respondent contends that this conclusion is not supported by the expert testimony of Dr. Scott nor the testimony of the user-witnesses who read Respondent's promotional material. It further contends that the rights of cross-examination and confront-ation of witnesses have been denied because the facts in support of this conclusion are omitted.

As discussed supra, Dr. Scott's tes-timony regarding the meaning of Respondent's promotional materials is unpersuasive. The user-witnesses who testified in this pro-ceeding do not necessarily represent the viewpoint of the ordinary reader at whom

these materials were directed. This group of users constitutes a selected portion of the community which may reasonably be considered more sophisticated than the ordinary interested reader of Respondent's materials. However, the purpose of the postal statutes is to protect the gullible as well as the wary reader. Fort Morgan Vapor Jet, P.S. Docket No. 12/64 (P.S.D. Sept. 29, 1982 at 9.)

Further, the reactions of these witnesses to Respondent's promotional materials varied. (Cf. Tr. 225-226, 303; Cose Dep. 7; O'Neill Dep. 9). The difference between whether the products "might" have a particular result and wether they "would" have that result would be a very fine point when viewed in the context of a more gullible reader who is concerned about his hair condition.

Finally, as discussed, the Administra-

tive Law Judge was authorized to review these promotional materials, independent of the testimony, and form his own conclusions regarding the representation made or implied. "Whether particular advertising has a tendency to deceive or mislead is obviously an impressionistic determination." Beneficial Corp. v. F.T.C., supra, 542 F.2d at 617; Vibra-Brush v. Schaffer, supra. A review of these materials confirms the conclusion that Respondent represents its products will cause the regrowth of hair on bald heads, as alleged in paragraph 3b of the Complaint.

Respondent also takes exception to the Administrative Law Judge's statement that "The text is cleverly laced with notes of skepticism and reports of isolated failures ..." Respondent contends that the term "cleverly laced text" "imputes to the Respondents a quality of

fraud, deception and intent to mislead readers of the material ...It is really impossible to use this cleverly laced text argument since the promotional material was written by individuals totally unassociated with the Respondents" (Resp. Appeal Brief at 24).

While the record indicates that Respondent was not involved in the initial authorship of these articles, it appears that the articles were subsequently altered as promotional material. In this regard, the two reprints of the Sacramento Bee article which comprise CX-2(a) and 3(d), page 1, are not entirely identical. The reprint of this article at CX-3(d) deletes a portion of the statements by Dr. Arthur Huntley, a dermatologist for the University Medical Center which is included in CX-2(a). The deleted except attributes the following statements to Dr. Huntley:

"The research findings, he pointed out, haven't been published in reputable medical journals despite the fact that some of them date to 1974. Secondly, Murphy's study hasn't followed normal medical research procedures.

"'If anything's any good, it has to pass the test of a double blind study.' He said 'It has to be tested by both patients and doctors who don't know what they're using and what results are expected.'

"'There's no question,' Huntley added, 'that if you want to see results you're going to see it whether it's there or not. Particularly with something as emotional as hair loss.'"

Further, the reprint at CX-2(a) references a conclusion by Finnish skin doctors "that it was possible to rejuvenate hair in 60% of the 320 people tested." However, the reprint of what is purportedly the same article appearing at CX-3(d) states that these doctors "concluded that it was possible to rejuvenate hair in 80% of the 320 men and women tested that had male pattern baldness."[2/] A comparison of the two articles discloses other differences.

In contrast, Respondent states, with regard to this article: "The article is reproduced by Respondents as written. Nothing in the article is highlighted or downplayed from the original" (Resp. Response Brief 14).

Differences also appear between the two reprints of the article in the Sacramento Union which comprise CX-2(b) and CX-3(d), page 3. The article appearing at CX-2(b), in discussing Lt. Col. Charles Miller's experience with Respondent's products, states: "nineand a half months later, where there was bald, there is fuzz ..." However, the reprint appearing as CX-3(d) states: "Nine and a half months later, where there was bald, there is hair ..." (emphasis added).

These examples belie the argument that Respondent did not exercise control over the text of the articles. Whether these alterations constitute "cleverly laced

text", however, need not be addressed. As discussed supra, whether or not a misrepresentation is intentional or, indeed, clever is irrelevant in determining whether a violation of 39 U.S.C. 3005 exists. Accordingly, the reference to "cleverly laced text" has not been considered.

Finally, Respondent contends that this representation, if made, was not a material inducement for readers of the promotional material to purchase the products. Clearly, consumers would be induced to purchase by the representation that use of the products will result in regrowth of hair. The representation is material.

13. Exception to Conclusion of Law No. 3

This conclusion states, in part, that insofar as the expert and lay witnesses stated that Respondent's advertising and promotional materials do not represent the products will cause regrowth of hair on bald

heads, their testimony is rejected as "flying in the face of the obvious express and implied thrust of such materials, the fact that Respondent has received at least 6,000 orders for the products, and also as contrary to plain common sense." In support of this conclusion, the Administrative Law Judge cites testimony by Dr. Scott. Respondent contends that the Administrative Law Judge cannot substitute his own "common sense" for the testimony of the lay witnesses who are part of the group interested in baldness, that no finding of fact exists which states what the "express and implied thrust" of these materials is, and that Dr. Scott's testimony has been misrepresented.

The Administrative Law Judge's right independently to determine the representations made by Respondent's promotional material, and the impact of the lay

witness testimony, have been discussed supra. In reviewing and affirming this conclusion of law, the reference to "at least 6,000 orders for the products" has not been considered, as already discussed. Nor has Dr. Scott's testimony been found persuasive, although it is found that her testimony was not misrepresented by the Administrative Law Judge.

14. Exception to Conclusion of Law No. 4

This conclusion states, in part, that "based on the testimony and opinions of Complainant's medical expert witness, Dr. Kramer, conforming to the informed medical consensus, I find that the representation made by Respondent as to regrowth of hair on bald heads is false in fact." Respondent contends that Dr. Kramer only testified as to how the representation is viewed by the consensus of medical opinion and that a distinction must be made between that

consensus and a determination that the representation, in fact, is false. In Cosvetic Labs., et al., supra, it was recognized that:

> "A commonsense difference exists between acceptance of a claim by a consensus of the relevant medical or scientific community and the inherent truth of that claim. However, these two aspects of a claim are nonetheless tied to each other. The acceptance of a claim as true under the standards of the medical or scientific community is prima facie evidence that the claim is, in fact, true. Conversely, proof by the Complainant in a false representation proceeding that a claim has not been accepted by the medical or scientific community constitutes prima facie evidence of its falsity. The burden of rebutting this evidence thereupon falls on the Respondent, which must show that the claim is true despite the lack of acceptance." (P.S.D. at 14; citations omitted).

The cases cited by Respondent, all involving consideration of products under the Federal Food, Drug and Cosmetic Act, indicate the importance accorded to a consensus of qualified opinion. In the latest decision, United States v. Articles

of Food and Drug, etc., the 5th Circuit stated:

> "The United States need only show the lack of the proper reputation for safety and efficacy of the drugs and for safety of the food additive among the appropriate experts, or that what reputation there is, is not based on adequate studies." (518 F.2d 743, 746 (5th Cir. 1975)).

See also Research Laboratories, Inc. v. United States, supra, 167 F.2d at 416.

With respect to this case, Dr. Kramer admitted that Respondent's theories "may or may not be true, but you have to prove it" (Kramer Dep. 16). However, the testimony and evidence presented fell short of the type of disinterested, scientific proof required. Cf. Porter and Dietsch, Inc. v. F.T.C., 605 F.2d 294, 302, 305-306 (7th Cir. 1979), which sustained a provision of a Federal Trade Commission Order prohibiting representations about the effectiveness of a product unless they are supported by "competent

scientific or medical tests or studies."

Respondent also takes exception to the conclusion's reference to the Setala/ Schreck-Purola study (CX-7) and its underlying theory that cholesterol is converted in the scalp to testosterone. Respondent asserts that both the study and the theory are irrelevant to this proceeding. This argument was discussed supra, in connection with Finding of Fact No. 17. Conclusion of Law No. 4 is affirmed.

15. Exception to Conclusion of Law No. 5

This conclusion states the basic legal principle that "expert opinion testimony need not be based on tests of the particular product in issue to constitute sufficient evidence of false advertising representations." Despite Respondent's contention to the contrary, the cases cited by the Administrative Law Judge clearly support this principle.

In Reilly v. Pinkus, 338 U.S. 269, 274 (1949), the Supreme Court specifically rejected the contention "that even the testimony of the most experience medical experts can never rise above a mere opinion' unless the expert has made actual tests of the drug to determine its effects in relation to particular representations alleged to be false." This position was favorably cited in Original Cosmetics Products, Inc. v. Strachan, 459 F. Supp. 496, 504 (S.D.N.Y. 1978), aff'd 603 F.2d 214 (2nd Cir. 1979), cert. den. 444 U.S. 915 (1979). See also Research Labs. v. United States, supra, 167 F.2d at 416, which recognized that "In this circuit and elsewhere, it has been held that expert testimony even in its broadest sense - i.e., where the witness has neither tested the product nor purports to report the consensus of medical opinion

- is admissible on the question of therapeutic value." Accordingly, this conclusion of law is affirmed.

16. Exception to Conclusion of Law No. 6

This conclusion states the principle that "a finding of falsity can be based on the testimony of informed medical or scientific opinion when there is no contradictory evidence which is said to be in accord with such a consensus of opinion." Respondent's contention that this principle is not supported by case law is without merit. See U.S. Health Club, Inc. v. Major, 292 F.2d 665 (1961); Owen Labs., Inc. v. Schroeder, 284 F. 2d 445 (1960); Research Labs. Inc., v. United States, 167 F.2d 410, 416 (9th Cir. 1948). Indeed, courts have recognized that a finding of falsity may be made even where a conflict in the medical testimony has been presented. See, e.g., Kurzon v. United States Postal Service, 539 F.2d

788 (1st Cir. 1948); Baslee Products Corp. v. United States Postal Service, 356 F. Supp.841, 850 (D.N.J. 1973); Reilly v. Pinkus, supra; United States v. Kaadt, 171 F.2d 600, 603-604 (7th Cir., 1948). Accordingly, this conclusion of law is affirmed.

17. Exception to Conclusion of Law No. 7

This conclusion rejects Respondent's argument that its representations concern an area that has not been "crystallized in the crucible of experience" and that they therefore cannot be found false under American School of Magnetic Healing v. McAnnulty, 187 U.S. 92 (1902). The Administrative Law Judge distinguished McAnnulty in that:

> "There are not at the present time, and consequently, there are not reflected in this record, two widely held schools of opinions as to whether a scalp product, such as Respondent's, containing polysorbate 60 will cause regrowth of hair.

> Only one real school of opinion-medical consensus established through Dr. Kramer-has been shown here. The linchpin of that consensus is that cholesterol is not converted in the scalp to testosterone. Therefore, removal of cholesterol from the scalp by polysorbate 60 has no influence on hair fall-out or regrowth." (I.C. pp. 17-18)

Respondent contends that the Administrative Law Judge has misconstrued the protection granted by McAnnulty and that he improperly based his conclusion on the cholesterol theory referenced earlier. The Judge's analysis of the McAnnulty case set forth in this conclusion is correct. That case, as characterized in the subsequent Supreme Court case of Reilly v. Pinkus, supra, concerned two distinct, widely held schools of opinion. This is not the situation here. While the Administrative Law Judge's sole emphasis on the cholesterol theory may not be justified by the record, it is

nonetheless true, as discussed, that Respondent has not presented any theory that would approach the level of acceptance of the opinions advanced by Dr. Kramer. Respondent's own expert witness, Dr. Ballard, presented his own theory as a mere "hypothesis" (Tr. 262) and indicated agreement with the "prevailing view" that the Setala/Schreck-Purola theory is erroneous (Tr. 261-262). Under these facts, the principles set forth in McAnnulty do not apply.

In so holding, the Postal Service is not condemning new ideas without a trial, as Respondent implies. As stated in Cosvetic Labs., et al., supra (P.S.D. at 15):

> "These findings and conclusions should not be construed as a condemnation of any new idea put forth by Respondent with respect to the treatment of the hair and scalp or as discouraging further

> scientific inquiry. Rather, they are solely directed at the particular representations made by Respondent in its advertisements, which go far beyond characterizing the products as ideas 'where knowledge has not yet been crystallized in the crucible of experience.'" Citing Reilly v. Pinkus, 338 U.S. at 274.

Accordingly, this conclusion of law is affirmed.

18. Exception to Conclusion of Law No. 8

This conclusion states, in part, that although the user-witnesses "appeared to be honest and attempting to tell the truth, their accounts were purely anecdotal, not rising to the level of valid, scientific proof for the important claim at issue." Respondent's contentions that the photographs of these witnesses are "unchallengeable"; that the witness's unimpeached testimony should be accepted as evidence that the products work; and its exception to the conclusion's reference to lack of scientific supervision or

controls have been addressed earlier.

Respondent notes an inconsistency between this conclusion's statements that the witness's reports "were consistent with a possible placebo effect, particularly since they were told before use of the product that it might produce new growth" (emphasis added) and Finding of Fact No. 18, which states that these witnesses were told that use of the products would result in new hair growth. As discussed supra, the cited portion of Finding of Fact No. 18 has not been totally accepted. The finding that all of the user-witnesses were told the products "might" produce new growth is similarly modified. However, Respondent made no attempt to eliminate the placebo effect. Therefore, the possibility of a placebo effect cannot be disregarded. Accordingly, this conclusion of law is affirmed, except as

modified.

19. Exception to Conclusion of Law No. 10

This conclusion states in part that Dr. Ballard's testimony did not establish that Respondent's product is effective "to achieve the results represented." Respondent's exception to the quoted phrase as signifying regrowth of hair has been addressed earlier with respect to Conclusion of Law No. 2(a).

20. Exception to Conclusion of Law No. 11

This conclusion states that while Respondent's product may produce the results represented, "in the present state of medical and scientific knowledge there is no reliable support for such claims such as to overcome the contrary consensus expressed by Dr. Kramer." Respondent contends that Complainant has failed to show, based on the present state of medical and scientific

knowledge, that its products do not have the effect represented. This argument has been addressed earlier. However, Respondent correctly points out that the Initial Decision does not specifically state that Complainant has proven its case by a preponderance of the evidence. It is concluded, based on a review of the entire record, that Complainant has met this burden with respect to the allegation set forth in Paragraph 3b of the Complaint. This conclusion is based on Dr. Kramer's testimony that Polysorbate 60, the active ingredient in Respondent's products, would not cause new hair growth (Tr. 37-38, 45); that the use of the shampoo and hair and scalp cleanser together would not cause new hair growth (Tr. 46); and that his views are consistent with the consensus of informed medical opinion (tr. 66). It is also based on Dr. Ballard's testimony that the

theory that Polysorbate 60 removes dihydrotestosterone is merely a hypothesis (Tr. 260-262). Accordingly, this conclusion of law is affirmed.

21. Exception to Conclusion of Law No. 12

This conclusion states the legal principle that "disclaimers are ineffective to rebut misrepresentations." Respondent contends that relevance of this conclusion is unclear, since the Administrative Law Judge does not use the term "disclaimer" in his findings of fact.

It is presumed that the term "disclaimer" refers to the negative or skeptical statements contained in the newspaper articles which were made a part of Respondent's promotional materials. The Administrative Law Judge is correct in concluding that such statements do not absolve Respondent from responsibility for making representations as to the products'

positive effects. While Respondent argues that the cases cited in support of this conclusion, Gottlieb v. Schaffer, 141 F. Supp. 7 (S.D.N.Y. 1956) and Cates v. Haderlein, 189 F.2d 369 (7th Cir., 1951), are inapposite because they concerned, respectively, inconspicuous and intentional disclaimers, the principle is not so limited. Both of these cases recognize that the entire advertisement must be examined in order to determine the effect of any disclaimer. As the 7th Circuit stated in Cates v. Haderlein:

> "The buying public does not ordinarily carefully study or weigh each word in an advertisement. . . the important criterion is the net impression which the advertisement is likely to make upon the purchasers to whom the advertisement is directed. ..." (189 F.2d at 373).

In this case, the "skeptical" portions of Respondent's promotional materials

(which, as discussed, were in at least one instance altered) are not sufficient to offset the much more boldly stated representations regarding the products. Accordingly, this conclusion of law is affirmed.

22. Exception to Conclusion of Law No. 13

This conclusion states that "Respondent's offer of a refund to dissatisfied purchasers does not overcome the effects of making false representations." Respondent contends that the case cited by the Administrative Law Judge, Borg-Johnson Electronics v. Christenberry, 169 F. Supp. 746 (S.D.N.Y. 1959), is not applicable to this case, because Borg-Johnson Electronics only addressed instances where "it appears that an advertiser deliberately induces its patron to purchase its products in the belief that its value far exceeds its true

worth" (Resp. Appeal Brief at 43, citing Borg-Johnson Electronics, 169 F. Supp. at 75). Respondent construes this principle too narrowly. The question of whether a false representation has been made is independent of whether the advertiser will make restitution to a disgruntled customer who is sufficiently motivated to seek it. Accordingly, a guarantee does not negate the falsity of a misrepresentation regardless of the advertiser's intent. See, e.g., Athena Products, Ltd., P.S. Docket No. 7/99 (P.S.D. Sept. 8, 1977); International Sewing Machine Distributors, P.S. Docket No. 5/64 (P.S.D. Sept. 8, 1977). Cf. Porter and Dietsch, Inc., v. F.T.C., supra, 605 F.2d at 302. This conclusion of law is affirmed.

23. Exception to Conclusion of Law No. 14

This conclusion states that "Respondent is engaged in a scheme to obtain

money through the mail by means of materially false representations in violation of 39 U.S.C. 3005." In view of the discussion in connection with Respondent's previous exceptions, Respondent's contention that this conclusion is unsupported by the record does not warrant further discussion. This conclusion of law is affirmed.

II. JUDICIAL OFFICER'S AUTHORITY

Respondent contends that the role of the Judicial Officer in this proceeding is limited to determining if the Initial Decision is supported by substantial evidence. It is well established that the preponderance of the evidence test is applied by the Judicial Officer in these proceedings. Telex and twx Directory, P.S. Docket No. 13/6 (P.S.D. April 1, 1983 and cases cited therein at pp. 5-7). Accordingly, the record in this appeal has been reviewed to determine if the

Initial Decision is supported by the preponderance of the evidence.

III. Complainant's Exception to the Initial Decision

Complainant takes exception to Conclusion of law 2(b), which found, in part, that Respondent's advertising and promotional materials did not make "in any serious or material manner" the representation alleged in Paragraph 3a of the Complaint that "New Generation Hair and Scalp Cleanser and New Generation Shampoo will stop hair loss in balding men." The Administrative Law Judge found that Respondent's materials make the representation "that the product will stop excessive loss of hair, not that it will stop hair loss as alleged in the Complaint. There was no motion by Complainant to conform pleadings to proof. I do not consider it fair and appropriate to amend the

Complaint at this juncture."

Complainant contends that the Complaint's reference to stopping "hair loss" should be construed as meaning "excessive hair loss", since even individuals without a hair loss problem "lose" on the average between 50 and 100 strands of hair each day, citing Dr. Kramer's testimony (Tr. 18). In this regard, Complainant argues that a man would only complain of hair loss if the number of strands lost exceeded the number replaced or, in other terms, was "excessive". "Conversely, if the signs of the balding process were to cease, he might well be heard to say that his hair loss has stopped, even though it would be more accurate to say that his hair loss was returned to normal" (Comp. Appeal Brief, p. 2). In the alternative, Complainant argues that it should be

allowed to amend the Complaint to conform to the evidence.

Paragraph 3a of the Complaint alleges that Respondent represents its product "will stop hair loss in balding men" (emphasis added). The underscored language makes clear that the term "stop hair loss" as used in this paragraph is intended to be defined within the limited context of male baldness. In this regard, while Dr. Kramer stated that a "normal" individual will lose between 50 and 100 hairs on an average day (Tr. 19), his testimony supports the common sense observation that baldness - and particularly male pattern baldness - is associated with hair loss in excess of this amount (Tr. 19-22).

Indeed, Respondent has conceded that the definition of "hair loss in balding men" is excessive hair loss, stating: "Complainant first states that the phrase

in the Complaint 'will stop hair loss in balding men' is descriptive of the hair loss relevant to this type of proceeding, i.e., a loss of hair that exceeds normal replacement and ultimately results in baldness. Obviously this must be the case, since if the rate of hair loss exceeds the rate of hair replacement, there will be a lessening of the number of visible hairs on the scalp and the perception of baldness, if not the reality, will set in" (Resp. Reply Brief 3).

It is therefore concluded that the parties understood, within the specific context of this proceeding, that "hair loss in balding men" meant excessive hair loss and tried this issue accordingly. In this regard, Mr. Murphy stated at the hearing that in his opinion use of Respondent's products will "stop excessive hair fall-out which is where you

get your thinning hair and eventually balding" (Tr. 211-212). It is also noted that, aside from arguing that Complainant was lax in its pleading, Respondent has not demonstrated any prejudice resulting from trial of this issue.

It is found that Respondent represented that the products will stop excessive hair loss by the language in CX-2(c) that "almost 100% have realized an end to abnormal 'fall-out' within three to four weeks." See also CX-2(b), which states that "nearly 100% have reported a slow-down or stopping of hair fall out." Similarly, see CX-3(d), p. 3.

It is further found that this representation has been shown to be false by a preponderance of the evidence because of Dr. Kramer's testimony that these products would not have any effect on preventing excessive hair loss (Tr. 46, 64) and that his views

are consistent with the consensus of informed medical opinion (Tr. 66). For the reasons discussed supra, this testimony was not offset by the evidence and testimony presented by Respondent. In view of the conclusion that the issue of excessive hair loss falls within the language of Paragraph 3(a) of the Complaint, the question of amending the Complaint to conform to the evidence is moot. Cf. Sales Unlimited, P.S. Docket No. 12/147 (P.S.D. Oct. 26, 1982). Conclusion of Law No. 2(b) is reversed.

IV. RESPONDENT'S MOTION TO REOPEN THE HEARING

Respondent has filed a Motion to Reopen the Hearing to determine the continuing effect, if any, of the advertising and promotional material on which the Complaint and the Initial Decision were based. In this regard, Respondent argues that over two years have transpired since the Sacramento

Bee advertisement and that the advertisement could only have had a local impact. It further argues that before a stop order can be issued, a determination must be made as to how many products were ordered in response to the Sacramento Bee advertisement. Complainant argues that a stop order which covers reorders as well as initial orders for the products would not be overbroad, but that it does not oppose Respondent's Motion so long as another evidentiary hearing is not involved. Respondent has also requested that the hearing be reopened in order to adduce additional testimony with respect to Conclusion of Law No. 2(a).

No further testimony is required with respect to Conclusion of Law 2(a) and, therefore, the record will not be reopened in connection with that conclusion. With respect to the continuing

impact of these advertising and promotional materials on current sales of Respondent's products, it would seem that through the good faith efforts of the parties the matter could be resolved by agreement. Accordingly, this matter is remanded to the parties for consideration of such an agreement. In the interim, a False Representation Order will be issued, but the return portion will be stayed pending a final determination of the impact issue. Such an Order with a Supplement A thereto is issued with this decision.

Signature
James A. Cohen
Judicial Officer

FOOTNOTES

1/ Complainant properly argues that if any portion of Dr. Schreck-Purola's testimony was admitted, all of the testimony should be admitted. The Administrative Law Judge agreed (Tr. 240). Logically all of Inspector Powers' testimony should be admitted as well.

2/ The article at CX-2(a) - but not the one at CX-3(d) - makes clear that the women in the test, who achieved a 100 percent return rate, had lost their hair during pregnancy. These women therefore could not be considered to have had a condition similar to male pattern baldness.